UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ST. PAUL ELECTRICAL WORKERS' HEALTH PLAN, on behalf of itself and all those similarly situated, *Plaintiff,* v. ABBVIE INC., ABBVIE BIOTECHNOLOGY LTD, and AMGEN INC., *Defendants.*	Civil Action No. _____ CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND

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I. INTRODUCTION

1. AbbVie's drug Humira has been the best-selling drug in the United States for six years running, bringing in more than $13.6 billion in sales in the U.S. in 2018 and nearly $20 billion worldwide. The original patent on Humira, a biologic drug approved in the U.S. in 2002, expired in late 2016, which should have led to competition for Humira prescriptions from manufacturers of biosimilar drugs. Biologics and their biosimilars are relatively new, but in many respects, they are similar to traditional brand and generic drugs. The effect of generic competition on brand drugs is well-established: once competition begins, brand sales fall rapidly as the generics compete on price with the brand. Prices continue to decrease as more generic competitors enter the market. The same basic principles apply to biologics, and a similar reduction in Humira's market share and a substantial drop in revenues from the drug would follow entry by biosimilar versions of Humira.

2. Humira generates approximately half of AbbVie's revenues, making the company's profitability highly dependent on its Humira sales. AbbVie has other drugs in the pipeline but sales (and attendant revenues) of those drugs would not begin until many years after the Humira patent expired, which would have left a void to fill if competition for Humira began in late 2016. So, AbbVie developed a plan to bridge the gap.

3. First, AbbVie created a virtually impenetrable patent thicket—an "absolute minefield of IP"—to snare and mire down any potential competitor. The more patents—valid or not—to contend with, the longer AbbVie could keep competition for Humira at bay and thus the longer Humira could command supra-competitive prices. AbbVie now has filed more than 240 patent applications and obtained well over 100 patents ostensibly covering Humira. The vast majority of these issued in 2014 or later, even though Humira was approved and hit the market twelve years earlier. Many of AbbVie's patents have clear deficiencies; for example, some of

AbbVie's patents have been invalidated by the U.S. Patent and Trademark Office. But the patents served AbbVie's purpose: creating a thicket so dense that competitors would have to engage in costly and time-consuming litigation over dozens upon dozens of patents before they could launch competing products.

4. AbbVie has been open about its intentions to use this patent thicket to delay potential competition, talking publicly about its "U.S. patent estate" and the fact that the "bulk of [the] IP strategy . . . is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar biosimilar." Bogging potential competitors down in litigation over the patents meant years-long delay: AbbVie's CEO told investors that "[a]s you evaluate the timeframe for a potential U.S. biosimilar market entry, it is important that you consider the legal process and the likely timeline for resolution . . . . [B]ased on similar cases, the total litigation timing may be as long as four or five years."

5. AbbVie used the patent system to make the costs to any potential competitor so high that the would-be competitor would not become an actual competitor. Despite the patents' weaknesses—and despite the fact that AbbVie frequently asserted patents that it had no basis to believe were infringed because many of them claimed Humira-like compounds but not Humira or the biosimilars themselves—the sheer volume of patents and claims in AbbVie's patent arsenal frustrated biosimilar companies' efforts to come to market.

6. Second, AbbVie paid a potential competitor to delay entry even further. At least nine companies have indicated an intent to market biosimilars to compete with Humira. Three currently have approval from the FDA. But none have launched. Instead, AbbVie entered into deals with each to delay their entry until various dates in 2023.

7. Not everyone has the same 2023 entry date, though. Amgen was the first biosimilar competitor to receive FDA approval, but was not entitled under the regulatory framework to any period of exclusivity during which it would be the only biosimilar on the market. In exchange for Amgen dropping its challenges to AbbVie's patents and agreeing not to launch its biosimilar product until January 2023, however, AbbVie provided Amgen with a *de facto* exclusivity by agreeing not allow other biosimilars to enter the market within five months of Amgen. Amgen thus will have five months as the only biosimilar on the market, enabling it to charge higher prices and realize hundreds of millions of dollars in higher profits than it would if it faced competition during this period. The pay-for-delay deal between AbbVie and Amgen was anticompetitive and unlawful.

8. Because of AbbVie's unlawful scheme and monopolization of the market, AbbVie has continued to reap the benefits of being the exclusive seller of Humira on the U.S. market, even though the primary patent on Humira expired at the end of 2016 and the FDA has approved several biosimilars to compete with Humira. Absent AbbVie's patent thicket and its pay-for-delay deal with Amgen, competition for Humira would have begun as early as the end of 2016, when the original composition patent for Humira expired. Because of AbbVie's unlawful scheme and the delay it bought from Amgen, Humira's sales have not yet faced competition and may not face competition until 2023. Under this scheme, AbbVie and Amgen win. Humira purchasers lose.

9. The plaintiff, St. Paul Electrical Workers' Health Plan ("Plaintiff" or "SPEW") and class members are end-payers for Humira. They are the last links in the pharmaceutical distribution chain, and they paid overcharges for Humira as a result of AbbVie's anticompetitive

conduct and Amgen's agreement not to compete with AbbVie. This action seeks to recover those overcharges for the plaintiffs and all similarly situated.

II. PARTIES

10. Plaintiff St. Paul Electrical Workers' Health Plan, located in St. Paul, Minnesota, is a jointly administered Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in St. Paul, Minnesota. The St. Paul Electrical Workers' Health Plan provides health benefits, including prescription drug benefits, to approximately 6,800 persons, including active plan participants and their spouses and dependents. St. Paul Electrical Workers Health Plan paid for Humira in class state(s) during the class period.

11. Defendant AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs. AbbVie Inc. is the holder of Biologic License Application ("BLA") No. 125057 for Humira, whose active pharmaceutical ingredient is the antibody adalimumab.

12. Defendant AbbVie Biotechnology Ltd. is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM1l, Bermuda. Through intermediate organizations, defendant AbbVie Inc. owns defendant AbbVie Biotechnology Ltd. Defendant AbbVie Inc. and defendant AbbVie Biotechnology Ltd. are collectively referred to herein as "AbbVie."

13. All of the actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, or undertaken by AbbVie's officers, agents, employees, or other representatives while actively engaged in the management

of AbbVie's affairs and within the course and scope of their duties and employment or with AbbVie's actual, apparent, or ostensible authority.

14. Defendant Amgen Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at One Amgen Center Drive, Thousand Oaks, California, 91320-1799. Amgen Inc. is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs. Amgen Inc. is the holder of Abbreviated Biologic License Application ("ABLA") No. 761204 for Amjevita, whose active pharmaceutical ingredient is the antibody adalimumab-atto.

III. JURISDICTION AND VENUE

15. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) and 15 U.S.C. § 15. This action alleges violations of sections 1 of the Sherman Act, 15 U.S.C. § 1, and seeks injunctive relief. Those violations are actionable under section 16 of the Clayton Act, 15 U.S.C. § 26. The Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), 1337(a), and 1367.

16. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) & 22 and 28 U.S.C. §§ 1391(b), (c), and (d). During the class period (December 31, 2016, to the present), AbbVie resided, transacted business, was found, or had agents in this District.

17. This Court has personal jurisdiction over AbbVie and Amgen. AbbVie and Amgen's wrongful conduct had a substantial effect on interstate commerce of the United States, including in this District. During the class period, AbbVie manufactured, sold, and shipped Humira in a continuous and uninterrupted flow of interstate commerce, which included sales of Humira in and from this District, advertisement of Humira in media in this District, monitoring prescriptions of Humira by prescribers within this District, and employment of product detailers in this District, who as agents of AbbVie marketed Humira to prescribers in this District. AbbVie

and Amgen's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this District.

18. Throughout the United States and including in this District, AbbVie and Amgen transacted business, maintained substantial contacts, or committed overt acts in furtherance of the illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. REGULATORY BACKGROUND

A. The federal regulatory structure encourages competition among drug companies.

19. Drugs generally fall into one of two categories: small molecule drugs and biologic drugs.[1] Small molecule drugs constitute the majority of drugs on the market and are manufactured using chemical processes. Biologics, in contrast, are derived from biological sources such as animals or microorganisms; the resulting molecules are much larger and more complex.[2] Federal regulatory frameworks guide the approval and marketing of both brand name small molecule and biologic drugs as well as their follow-on competitors: generic drugs and biosimilars, respectively. The frameworks, while slightly different, share overarching goals: fostering innovation and promoting price competition for the benefit of consumers.

20. Biologics are very expensive drugs. According to a 2017 Rand Corporation study, although only 1–2 percent of the U.S. population is treated with a specialty drug each year—a category that includes biologics—biologics alone accounted for 38 percent of U.S.

[1] Biologic drugs are sometimes referred to as biopharmaceuticals.

[2] FDA, *What Are "Biologics" Questions and Answers*, (Aug. 5, 2015), http://www.fda.gov/aboutfda/centersoffices/officeofmedical.

prescription drug spending in 2015 due to their high cost per dose, and for 70 percent of drug spending growth between 2010 and 2015.[3]

21. The Biologics Price Competition and Innovation Act of 2009 was enacted to accelerate competition with a legal pathway for generic versions of biologic drugs (called biosimilars) to come on the market, after a 12-year period of exclusivity for the original biologic drug.

1. The Hatch-Waxman Act allows for approval of generic versions of small molecule drugs and enables competition with their brand counterparts.

22. Small molecule drugs have been regulated under the Food, Drug, and Cosmetics Act ("FDCA") since 1938. Pursuant to this statute, drug companies that wish to sell a new small molecule drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include specific data concerning the safety and efficacy of the drug to allow the FDA to determine whether to approve it for public consumption. The first version of a small molecule drug to receive FDA approval is typically provided with a brand name by its manufacturer and marketed under that name.

23. In 1984, Congress amended the FDCA with the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.[4] The Hatch-Waxman Act "sought to balance two competing policy goals: (1) encouraging the development of generic drugs to increase competition and lower prices in the pharmaceutical industry, while (2) maintaining incentives for pharmaceutical companies to invest in innovation and the creation of new drugs."

[3] Rand Corporation, "*Biosimilar Cost Savings in the United States*," available at https://www.rand.org/pubs/perspectives/PE264.html

[4] Pub. Law No. 98-417, 98 Stat. 1585 (1984).

24. Among other things, the Hatch-Waxman Act created a shorter pathway for approval of generic drugs than for the approval of the original brand name drugs. A generic drug manufacturer may submit an Abbreviated NDA (an "ANDA"). The ANDA applicant can save substantial time and money by relying upon the safety and efficacy studies previously submitted as part of the NDA for the brand drug. But it must demonstrate that its generic drug is bioequivalent to the previously approved drug product—that it has the same active ingredient, maximum amount of active ingredient in the bloodstream at any given time, strength, dosage, and route of administration (tablet, injection, etc.). And to market its potential generic, the ANDA applicant must wait until any patents and exclusivities enjoyed by the brand manufacturer expire or are otherwise no longer obstacles.

25. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to compete with and use in place of the brand drug. Without generic competition, the brand manufacturer can continue to profitably charge supra-competitive prices. The introduction of a generic drug, however, results in a predictable and rapid loss of revenue for the brand drug seller.

26. Experience and economic research show that the first generic manufacturer to launch tends to price its product only slightly below the price of the branded counterpart. Once additional generic competitors enter the market, price competition between the generic competitors drives prices down significantly. Multiple generic sellers typically compete vigorously over price, driving prices down toward marginal manufacturing costs.

27. The Hatch-Waxman Act includes an incentive to generic drug manufacturers to challenge suspect patents and seek early approval of generic alternatives to brand drugs. The first generic drug manufacturer to file an ANDA and make a particular certification regarding the

patents purportedly covering the brand drug receives a 180-day period to market the generic version of the drug, free from competition from other generic versions of the drug approved through the ANDA process. During this time, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same drug. This permits the generic "first filer" to monopolize the generic market for those 180 days and charge a significantly higher generic price than would prevail with full generic competition. The majority of a generic manufacturer's profits accrue in these 180 days, leading the Supreme Court to recognize in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013), that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer generic.

28. This pathway has proved highly successful in producing greater competition, fostering the faster development of generic drugs and the attendant reduction in prices that competition brings. Prior to the Hatch-Waxman Act, only 35% of drugs faced generic competition after patent expiration, whereas now almost all do. Similarly, generic drugs are typically priced at a fraction of the cost of their brand counterparts, resulting in substantial savings for consumers and other payers of healthcare costs.

2. The Biologics Price Competition and Innovation Act likewise allows for approval of biosimilar drugs and enables competition with their biologic counterparts.

29. Biologics are not new; they include vaccines, first developed in the late eighteenth century. But technological advances in the past few decades have resulted in more biologics coming to market than ever before.

30. The approval process for a new biologic drug is also regulated by the FDCA and is similar to that for the brand name version of a small molecule drug. A manufacturer of a biologic may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in 42 U.S.C. § 262. The pathway for approval for new biologics is set forth in

42 U.S.C. § 262(a). Under that subsection, the drug manufacturer submits a Biologic License Application ("BLA"), which must include data similar to that included in an NDA; the FDA may license a new biologic if, among other things, the manufacturer demonstrates that it is "safe, pure, and potent."[5]

31. The statute also prescribes an alternative, abbreviated route for FDA approval of biosimilars, set forth in 42 U.S.C. § 262(k), enacted as part of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[6] While the first approved version of a small molecule drug is commonly known as the "brand name" drug, the BPCIA refers to the first approved version of a biologic as the "reference" biologic. Biosimilar versions of biologic products are in many ways similar to generic versions of brand name small molecule drugs.

32. The FDA has explained that the BPCIA "is similar to the way the Hatch-Waxman amendments sought to establish balance between innovation for brand products and availability of generic competition."[7] Likewise, legislators and the Obama Administration expressed that the primary purpose of the BPCIA was, like the Hatch-Waxman Act, to promote competition by increasing the number of biosimilars in the market. For example, in its proposed budget released in February 2009, the Obama Administration noted that "[p]rescription drug costs are high and rising" and proposed "accelerate[d] access" with a "legal pathway for generic versions of biologic drugs."[8] Similarly, Senator Sherrod Brown stated, in June 2009, "[p]erhaps nowhere [is

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[5] 42 U.S.C. § 262(a)(2)(C)(i)(I).

[6] 124 Stat. 808.

[7] FDA, *Biosimilar Action Plan: Balancing Innovation and Competition*, (July 2018) https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM613761.pdf (last accessed March 7, 2019).

[8] *Office of Mgmt. & Budget, A New Era of Responsibility*, (2009), at 28, available at http://www.washingtonpost.com/wp-srv/politics/budget2010/fy10-new-era.pdf.

the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics . . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills."[9] Representative Frank Pallone noted "If biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like Hatch-Waxman did."[10]

33. The BPCIA created a shortened pathway for approval of biosimilars via an Abbreviated Biologic License Application ("ABLA").

34. To obtain approval, the applicant may piggyback on the showing made by the manufacturer of a previously licensed biologic ("reference product").[11] A biosimilar manufacturer must show that its product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."[12]

35. The BPCIA provides that an ABLA seeking approval of a biological product as a biosimilar must include information demonstrating that:

i. the biological product is biosimilar to a reference product based upon data derived from [certain kinds of studies];

ii. the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed,

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[9] 155 Cong. Rec. S6793 (daily ed. June 18, 2009).

[10] *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2009).

[11] *See* 42 U.S.C. § 262(k)(2)(A)(iii).

[12] 42 U.S.C. §§ 262(i)(2)(A), (B); *see also* 42 U.S.C. § 262(k)(2)(A)(i)(I).

recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

iii. the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

iv. the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

v. the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.[13]

36. A biosimilar company may not submit an ABLA for FDA approval until four years after the reference product is first approved, and the FDA may not approve a biosimilar until twelve years after the reference product is first approved.[14] As a result, the manufacturer of a new biologic enjoys a statutory twelve-year period when its biologic may be marketed without competition from biosimilars. After that point, no regulatory exclusivities exist that would prevent competition from biosimilars.

37. Unlike the Hatch-Waxman Act, the BPCIA does not allow for a period of exclusivity for the first biosimilar to seek to come to market. Rather, once the twelve-year period for biologic exclusivity has expired, the FDA may approve for marketing and sale any and all biosimilar products that meet the requirements.

B. Follow-on drugs (including biosimilars) have a real effect on competition.

38. The effect of competition for small molecule drugs is well-established. Once a brand drug company's lawful exclusivities over its patented drug expire and it faces generic competition, brand sales fall rapidly as the market shifts toward the less-expensive competitor

[13] *Id.* § 262(k)(2).

[14] 42 U.S.C. §§ 262(k)(7)(A), (B).

products. Without generic competition, a brand manufacturer can charge supra-competitive prices without fear of losing profits or market share. The introduction of a generic drug, however, results in a predictable and rapid loss of revenue and market share for the brand drug seller. Once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months after launch and 90% of the brand's unit drug sales after a year.

39. It does so by pricing at a discount. The first generic manufacturer to launch tends to price its product slightly below the price of the branded counterpart. Once additional generic competitors enter the market, price competition between the generics begins in earnest, with multiple generic sellers driving prices down toward marginal manufacturing costs.

40. According to the FDA and Federal Trade Commission, the greatest price reduction for pharmaceutical products arrives when the number of generic competitors goes from one to two. Typical estimates are that a single generic launch results in a near-term retail price reduction of 20% but once there are two generics, near-term price reduction may reach 50%. Prices continue to decline as more generic manufacturers enter the market.

41. This all results in dramatic savings for drug purchasers. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

42. Biologic and biosimilar drugs are newer to the U.S. marketplace. The FDA approved the first biosimilar in 2015 and only seven biosimilars of any drug are currently marketed in the United States. As such, less data exists concerning the impact of biosimilars as compared to the comprehensive information about ANDA-approved generics. While there are differences in distribution, substitution laws, and prescription writing between biosimilars and

generics drugs, the general principle is the same: competition from FDA-approved follow-on products lowers prices for consumers.

43. Numerous studies have been issued estimating the cost savings (determined by estimated price reductions, penetration, and the like) on the introduction of follow-on biologics and biosimilar drugs.

44. A 2014 study by the Rand Corporation canvassed existing studies estimating U.S. biosimilars' price impact and market penetration, as well as the overall savings they cause.[15] Combining the results of these studies, Rand estimated overall market penetration of 60%, and a biosimilar price discount due to competition of 35%. It acknowledged that the Congressional Budget Office anticipates an even larger 40% reduction in the long term. All studies reviewed by Rand anticipated some amount of substantial price decreases.

45. In 2017, Rand Corporation updated its earlier article based on empirical evidence from the emerging biosimilar market. It predicted that "biosimilars will lead to a reduction of $54 billion in direct spending on biologic drugs from 2017 to 2026."

C. New products may be protected by valid patents for a limited time, but not forever.

46. A drug company may hold patents covering a brand or biologic drug, its therapeutic uses, and the processes used to manufacture it, among other things. Such patents may constrain an ABLA applicant's ability to market its biosimilar even after the expiration of the BPCIA's twelve-year exclusivity period.

47. A patent must claim a novel invention. If the matter claimed in the patent application "was patented, described in a printed publication, or in public use, on sale, or

[15] Rand Corporation, *The Cost Savings Potential of Biosimilar Drugs in the United States*, (2014) available at https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf

otherwise available to the public before the effective filing date of the claimed invention," the application must be denied.[16] Prior patents, publications, and other publicly known material before the filing date of the patent are called "prior art."

48. As time passes, prior art accumulates: patents issue, publications reveal new discoveries, and new drugs go on sale. Thus, in general, later-filed patent applications face a greater volume of prior art than earlier-filed patent applications. One exception to this general rule is the "continuation application." If a company has a pending patent application, it may file a continuation application explicitly relating to the original (called the "parent") application and prosecute both the parent and the continuation. Each application may issue as a separate patent. Continuation applications have the same specification as their parent applications, but they add new, related claims.[17] They have the same effective filing dates (called their "priority dates") as their parent applications, so intervening advances in the art generally do not render them invalid for obviousness.

49. If the claims of the continuation patents are simple, obvious variations on the claims of the co-pending parent application, the applicant generally must file a terminal disclaimer under 37 C.F.R. § 1.321(b), relinquishing any portion of the new patent term that would extend beyond the life of the original patent. Failing to file a proper terminal disclaimer may result in rejection of application on the ground of obviousness-type double patenting, which is "primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent."[18]

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[16] 35 U.S.C. § 102(a).

[17] *See* 35 U.S.C. § 120; 37 C.F.R. § 1.78(d).

[18] Manual of Patent Examining Procedure § 804.

50. Patent prosecutions before the U.S. Patent and Trademark Office ("PTO") are non-adversarial. Accordingly, patent applicants are subject to special oaths and duties designed to protect the public's interest in the PTO's issuance of valid patents. Because patents usually enable a brand manufacturer to exclude competition and charge supra-competitive prices, it is crucial that any patent covering a brand drug or biologic be valid and lawfully obtained.

51. To help ensure the "public interest is best served" when the PTO issues a patent, patent applications are subject to the duties of disclosure, candor, and good faith, which requires the applicant to disclose to the PTO "all information known to be material to patentability," including any prior art.[19] This duty is imposed on those responsible for making the application, including each of the named inventors; each "attorney or agent who prepares or prosecutes the application"; and "[e]very other person who is substantively involved in the preparation or prosecution of the application."[20]

D. Regulatory frameworks permit challenges to drug patents.

52. Like the Hatch-Waxman Act, the BPCIA implicitly acknowledges that the biologic manufacturer (also known as the "reference product sponsor") may use the patent system inappropriately to forestall competition and lays out a framework for challenging patents that the reference product sponsor claims covers the reference biologic.

53. In general, a patent owner may not file an action for patent infringement until another person makes, uses, offers to sell, or sells the patented invention within the United States.[21] But the Hatch-Waxman Act and the BPCIA enable the reference product sponsor to

[19] *See* 37 C.F.R. § 1.56(a).

[20] *Id.* § 1.56(c).

[21] *See* 35 U.S.C. § 271(a).

bring an infringement action before the allegedly infringing drug is on sale. Both provide that the mere submission of application for FDA approval of a generic or biosimilar constitutes an act of infringement,[22] and both lay out procedures for resolving patent disputes.

54. Under the Hatch-Waxman Act, the brand manufacturer may submit a list of patents allegedly covering its drug to the FDA, which lists the patents publicly in a reference called the "Orange Book." But the equivalent reference for biologic drugs—the "Purple Book"—does not list patents. Instead, the BPCIA lays out a five-step set of pre-litigation exchanges (sometimes called the "patent dance") that may culminate in patent litigation if the parties do not resolve their disputes. It also provides remedies for this infringement, including injunctive relief and damages.[23]

55. First, no more than twenty days after the FDA accepts an application for review, the applicant must provide the ABLA and other confidential information about how the biosimilar is manufactured to the reference product sponsor.[24] This set of disclosures is sometimes called the "2A disclosure," named for the section of the BPCIA requiring this disclosure. These disclosures enable the reference product sponsor to evaluate the biosimilar for possible infringement of patents it holds.[25] The information the applicant provides is subject to strict confidentiality rules.[26]

56. Second, the parties exchange information to identify relevant patents and to flesh out the legal arguments that they might raise in future litigation. Within sixty days of receiving

[22] 35 U.S.C. §§ 271(e)(2)(C)(i), (ii).

[23] 35 U.S.C. § 271(e)(4)

[24] 42 U.S.C. § 262(l)(2)(A).

[25] 42 U.S.C. § 262(l)(1)(D).

[26] *See* 42 U.S.C. § 262(l)(1)(H).

the application and manufacturing information and based on a review of those materials, the reference product sponsor must respond with a list of patents for which it believes "a claim of patent infringement could reasonably be asserted" against the ABLA applicant if it made, used, offered to sell, sold, or imported "the biological product that is the subject of the [biosimilar] application" without a license.[27] This list of patents is sometimes called the "3A list." The reference product sponsor must also identify any patents on the 3A list that it would be willing to license.[28]

57. Third, within sixty days of receiving the 3A list, the ABLA applicant must provide to the reference product sponsor, for each patent, "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [ABLA] applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the" biosimilar or a statement that it "does not intend to begin commercial marketing of the [biosimilar] product before the date that such patent expires."[29] This statement is sometimes called the applicant's "3B statement." In the 3B statement, the ABLA applicant also must respond to the reference product sponsor's offer to license particular patents[30] and may provide to the sponsor a list of patents that the ABLA applicant believes are relevant but were omitted from the 3A list.[31]

58. Fourth, within sixty days of receiving the 3B statement, the reference product sponsor must reply with "a detailed statement" that, for each patent that the ABLA applicant

[27] 42 U.S.C. § 262(l)(3)(A)(i).

[28] 42 U.S.C. § 262(l)(3)(A)(ii).

[29] *Id.* § 262(l)(3)(B).

[30] 42 U.S.C. § 262(l)(3)(B)(iii).

[31] 42 U.S.C. § 262(l)(3)(B)(i).

identified as invalid, unenforceable, or not infringed, describes "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the [biosimilar] and a response to the statement concerning validity and enforceability provided" in the applicant's 3B statement.[32] This response is sometimes called the reference product sponsor's "3C statement."

59. By the conclusion of step four, which may be up to 200 days after the biosimilar manufacturer obtains FDA acceptance of its application to market a biosimilar, the parties have identified in this patent dance all of the patents whose validity, enforceability, and/or infringement that either party believes may be at issue and provided detailed explanations of the bases of their beliefs about why each is or is not invalid, unenforceable, and/or infringed.

60. Fifth, the parties attempt to negotiate a list of patents that "shall be the subject of an action for patent infringement[.]"[33] If they do not agree on a list within fifteen days of receipt of the ABLA applicant's receipt of the 3C statement, each party selects a list of patents (its "(*l*)(5) list") that will become the subject of a patent infringement suit.[34] The ABLA applicant may limit the number of patents on the (*l*)(5) lists: it must tell the reference product sponsor how many patents it will select, and the reference product sponsor cannot select a greater number of patents than the ABLA applicant.[35] No later than five days after the ABLA applicant notifies the

[32] *Id.* § 262(l)(3)(C).

[33] *Id.* § 262(l)(4).

[34] *Id.* § 262(l)(5).

[35] *Id.* If the ABLA applicant does not select any patents, the reference product sponsor may list one patent. *Id.* § 262(l)(5)(B)(ii)(II).

reference product sponsor of the number of patents it will select, the parties must simultaneously exchange their lists.[36]

61. Once the parties complete the pre-litigation exchanges, the first phase of BPCIA litigation begins. Under the statute, the reference product sponsor "shall bring an action" in court within thirty days of the date of agreement or the simultaneous list exchange.[37] This patent infringement action concerns the patents on the parties' (*l*)(5) lists, but it does not address the remaining patents.

62. A second phase of BPCIA litigation may address the remaining patents. The ABLA applicant must provide the reference product sponsor at least 180 days' notice before commercially marketing the biosimilar.[38] Upon receiving such notice, the reference product sponsor may file for a preliminary injunction prohibiting the manufacture or sale of the biosimilar until adjudication of the validity, enforcement, and/or infringement of any patent on the original 3A list.[39] The second phase of BPCIA litigation thus concerns all patents that the sponsor alleges are relevant.

63. Once the 180-day notice period has expired, and provided that the FDA has approved the ABLA, the ABLA applicant may launch its biosimilar regardless of whether the patent litigation has been resolved. Launch of a product that allegedly infringes patents before a final court decision on the validity and infringement of the patents is commonly called an "at-risk" launch. A manufacturer that launches at risk before a final court decision on the patents,

[36] *Id.* § 262(l)(5)(B)(i).

[37] 42 U.S.C. §§ 262(l)(6)(A), (B).

[38] *Id.* § 262(l)(8).

[39] *Id.* § 262(l)(8).

however, risks having to pay substantial damages to the brand or biologic manufacturer if the patents are found valid, enforceable, and infringed.

E. Biologic companies can abuse the patent system and BPCIA framework.

64. Brand drug and biologic manufacturers companies often develop their drug patent portfolios according to particular patterns. The first group of patents in a brand drug or biologic manufacturer's portfolio for a particular product may reflect a genuine technological breakthrough that may later contribute to the success of the drug. These initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition.

65. After filing their applications for the initial patents, brand drug and biologic manufacturers typically continue to seek other forms of patent protection, often filing for narrow modifications relating to specific formulations, methods of using the drugs, or processes for creating the drug products disclosed in the original patent filings. However, for these secondary patent filings, the original patents become "prior art," limiting the scope of follow-on patents that the manufacturers may obtain. A manufacturer may only obtain a *new* patent on a previously patented drug product if the specific feature for which the manufacturer seeks a new patent is non-obvious in light of the prior art (older patents, publications, and inventions). As the number of patent filings for the drug grows, so does the volume of prior art that a patent application must distinguish.

66. Therefore, a typical patent portfolio for a brand drug or biologic has its most significant patents issuing first. Later issued patents become increasingly narrow and more difficult to obtain. Even if narrower coverage is obtained, these later issuing patents are more vulnerable to invalidation for covering subject matter that is old or obvious. Competitors can also more easily design around narrower patent coverage, thus preventing the manufacturer from satisfying its burden of proving infringement to keep competitors out of the market.

67. Instead of following this normal course, for decades drug manufacturers have gamed the system by obtaining meritless patents to use as weapons against would-be competitors, even though such patents would not withstand challenges in court. A white paper examining federal district court patent cases in Westlaw and LexisNexis from 2007 to 2011 and that reached a disposition on the validity of a patent found that in more than 86% were the claims challenged in the patent determined to be invalid and/or not infringed. The biotechnology field, which includes biologic drugs, has an even higher invalidity rate. An academic paper that examined all substantive decisions rendered by any court in any patent case filed in 2008 and 2009 and found that biotechnology patentees won only 5.6% of the time. The authors concluded that their "data set suggests that the biotechnology patents that reach a merits ruling overwhelmingly lose." They added that, "[o]f the litigated patents in our data set, biotechnology patents are much more likely to be invalidated than any other type of patent, and they are less likely than average to be infringed."

68. Concerned enough that invalid patents were being issued and improperly enforced, to the detriment of both innovation and the economy, Congress passed the Leahy-Smith America Invents Act ("AIA") in 2011. A centerpiece of the AIA is the system of *inter partes* review, which allows patent challenges through an administrative process that differs from traditional patent litigation and expands the universe of potential patent challengers.

69. An *inter partes* review commences when a party—often an alleged patent infringer—petitions the Patent Trial and Appeals Board ("Board") to reconsider the PTO's issuance of an existing patent and invalidate it on the ground that it was obvious or anticipated by prior art. The petition cannot be based on other grounds for invalidity, such as inequitable conduct.

70. The Board will grant a request for an *inter partes* review only if the challenger of the patent shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[40] The Board must decide the review within one year of the institution date.

71. The system of *inter partes* review has not solved the problems associated with companies improperly obtaining and asserting patents. In July 2018, Scott Gottlieb, the Commissioner of the FDA, observed that biosimilar competition was "anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they'll be available to patients here. These delays can come with enormous costs for patients and payers."[41] He added that "patent thickets that are purely designed to deter the entry of approved biosimilars are spoiling this sort of competition."[42]

V. FACTS

72. The plaintiff, on behalf of itself and all others similarly situated, alleges the facts in the complaint on the basis of (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

A. Humira is the best-selling drug in the world and AbbVie's lifeblood.

73. "Humira" is an acronym for "Human monoclonal antibody in rheumatoid arthritis." Its active ingredient is adalimumab, an anti-inflammatory biologic medicine that binds to tumor necrosis factor alpha (TNFα). The inflammatory response of many autoimmune

[40] 35 U.S.C. § 314(a).

[41] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm.

[42] *Id.*

diseases is triggered when TNFα binds to TNFα receptors in the body. Humira interferes with that process, reducing the body's inflammatory response.

74. The antibody adalimumab was originally developed through a collaboration between BASF AG and Cambridge Antibody Technology. Formulations of adalimumab were disclosed in U.S. Application No. 08/599,226, filed on February 9, 1996, which issued as U.S. Patent No. 6,090,382 ("the '382 patent") on July 18, 2000. BASF AG was the original assignee for the '382 patent, which expired on December 31, 2016.

75. On March 2, 2001, AbbVie's predecessor Abbott completed its purchase of BASF AG's pharmaceutical business, acquiring the rights to adalimumab and the '382 patent.

76. Abbott obtained FDA approval for Humira in late 2002 and launched Humira shortly thereafter.

77. Although Humira was first researched and approved as a treatment for rheumatoid arthritis, it is now indicated to treat a range of other autoimmune conditions as well, including juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, and uveitis.[43]

78. Humira is administered by subcutaneous injection. Once acclimated, patients need to be injected, or to inject themselves, approximately every two weeks. Patients who start on Humira are advised to stay on it indefinitely. Indeed, patients are warned that if they abruptly stop treating with Humira, they may have a "severe" reaction or "flare up" of their condition and may not respond thereafter to Humira or other similar treatments. AbbVie's commercial efforts

[43] *See* Humira Label, December 2017, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125057s403lbl.pdf.

are focused on keeping existing patients on the drug without interruption for the long haul and obtaining new users.

79. Humira is one of the largest-selling drugs of all time in the United States (and worldwide), with its growth accelerating from entry to present day. The following table shows the sales of Humira since its launch in 2003.[44]

Year	U.S. sales	Worldwide sales
2003	•	$280,000,000
2004	•	$852,000,000
2005	•	$1,400,000,000
2006	$1,200,000,000	$2,000,000,000
2007	$1,600,000,000	$3,000,000,000
2008	$2,200,000,000	$4,500,000,000
2009	$2,500,000,000	$5,500,000,000
2010	$2,872,000,000	$6,508,000,000
2011	$3,427,000,000	$7,932,000,000
2012	$4,377,000,000	$9,265,000,000
2013	$5,236,000,000	$10,659,000,000
2014	$6,524,000,000	$12,543,000,000
2015	$8,405,000,000	$14,012,000,000
2016	$10,432,000,000	$16,078,000,000
2017	$12,361,000,000	$18,427,000,000
2018	$13,685,000,000	$19,936,000,000
TOTAL	$74,819,000,000.00	$132,892,000,000.00

80. Humira has been the top-selling drug in the U.S. for more than six years. It is not, however, the most prescribed drug; Humira was the 150th most-prescribed drug in 2016. Its immense revenue was due to its high price: at times during the period of exclusivity of the '382 patent, Humira has cost nearly $50,000 per patient per year.

[44] U.S. sales are not available until 2006.

B. AbbVie works to preserve its Humira profits at all costs, purposely creating a patent thicket to trap its would-be competitors.

81. AbbVie and its predecessor, Abbott, recognized that thwarting competition from biosimilars for as long as possible would be key to extending Humira's sales and AbbVie's profits. With enough patents tying potential competitors in knots, AbbVie could wield—and has been wielding—its patent thicket as an anticompetitive weapon: the sheer volume of patents and claims would deter biosimilar companies from seeking approval and litigating the patents to conclusion. Regardless of the ultimate merits, AbbVie could keep biosimilars off the market because few if any companies could litigate all of AbbVie's patents; indeed, few could even parse through the morass of patents to determine whether any were valid and infringed. And even if a company chose to do so, it would not obtain a final judgment for many years.

82. Meanwhile, even if a biosimilar company evaluated each and every claim of all known Humira patents and concluded that they were all invalid or not infringed, it might still be hesitant to launch at risk. If any of AbbVie's patent claims was held valid and infringed, the biosimilar company could be subject to crushing damages based on sales of the best-selling drug in the world. Thus, through its threats of protracted litigation, AbbVie could maintain its monopoly through its use of government process, regardless of whether it prevailed.

1. AbbVie has admitted that it sought to extend its exclusivity over Humira by several years by creating an elaborate thicket of patents.

83. AbbVie was created as a spinoff of Abbott's biologic and branded drug business in early 2013. AbbVie since inception has been highly dependent on Humira sales. The Chicago Tribune reported that "[i]nvestors . . . initially raised concerns that the spinoff was a way to separate Abbott from the looming liability presented by the 2016 U.S. patent expiration of Humira, which represent[ed] about half of the drug division's sales."

84. AbbVie publicly acknowledged that it was heavily dependent on Humira sales until it could develop new drugs. At the Goldman Sachs Healthcare Conference on June 13, 2013, shortly after AbbVie was spun off, AbbVie's EVP and CFO Bill Chase stated:

> [W]hat's beautiful about this business is *its relatively simple business model*, right. At the end of the day, *it's about making sure we achieve everything we can with Humira*, which has tremendous growth potential, and it's about making sure our pipeline ultimately is launched and delivers meaningful growth. So that's basically what we're aligned around. It's about those two things . . . .

85. Because it obtained approval for Humira in December 2002, AbbVie's twelve-year exclusivity under the BPCIA terminated in December 2014. AbbVie thus could not count on statutory or regulatory exclusivities to protect Humira. AbbVie knew and explicitly stated that patents on biologic drugs could deter biosimilar competition. On AbbVie's earnings call on October 25, 2013, AbbVie's CEO Rick Gonzalez noted that, in seeking to make a small handful of biosimilars:

> *[Y]ou're going to be walking your way through an absolute minefield of IP, thousands of patents around all of these products.* And you have to make sure that you don't step on any one of them along the way because that's going to create a big problem for you *because I can assure you just like us, every innovator is going to protect their patent position.*

86. Knowing that creating an "absolute minefield of IP" could deter competition, AbbVie sought to obtain as many patents as it could. Some of the patents claimed Humira, its uses, or its manufacturing processes. Other patents included ingredients, formulations, and/or processes that AbbVie did not use but which an innovative biosimilar company might employ to make a competitor to Humira. AbbVie sought to patent the entire field of Humira-like drugs so as to foreclose any possible competition. At the same time, AbbVie made every effort not to specify what patents it held or how it planned to utilize them. AbbVie has also admitted that its patent strategy is aimed not at securing legitimate patents on novel Humira uses and processes

but instead on making it difficult for any company to make a biosimilar that is sufficiently similar to Humira without infringing AbbVie's patents. At the Goldman Sachs Healthcare Conference on June 11, 2014, Mr. Chase stated to investors:

> Well, we do have a very robust collection of IP, and that IP certainly covers manufacturing process—a variety of different things. *And we're obviously not very specific about what's in there.* But let me—*suffice to say that, with a product as important and as attractive as Humira, you do everything you can on the IP front to ensure that you've protected it to the best you can*.
>
> *The bulk of that IP strategy, although there's a lot of strategies in there, is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar biosimilar.* Right? And the less similar, the greater likelihood of a difference in efficacy, or, very importantly, a difference in safety.

87. AbbVie acknowledged in 2015 that the "vast majority" of its patent thicket around Humira had been developed in the past two years—that is, since the split with Abbott in 2013. AbbVie also noted that patent litigation could delay competition (regardless of the outcome), and that a biosimilar was unlikely to launch during litigation because of the threat of "extremely large" damages. On AbbVie's earnings call on October 30, 2015, Mr. Gonzalez stated:

> Turning to our U.S. patent estate, . . . we have built a robust portfolio of intellectual property. *Beyond our composition of matter patent, we have more than 70 additional later-expiring U.S. patents related to HUMIRA. The vast majority of these patents . . . were granted by the U.S. Patent and Trademark Office within the past two years.* These patents expire between 2022 and 2034.
> . . .
> *Any company seeking to market a biosimilar version of HUMIRA will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously*. With respect to formulating the drug, we have patents on formulating the HUMIRA antibody, that also expire no earlier than 2022. Biologic drugs must be administered intravenously or as injections and can be difficult to formulate properly. Given our extensive experience with HUMIRA, *these patents cover not only our commercial formulation, but also other related formulations that biosimilar companies might employ.* 14 patents have been issued covering different formulations of HUMIRA.
> . . .

> Since the biosimilar statute requires the biosimilar to obtain approval for one or more indications previously approved for the innovator drug, and have the same route of administration, dosage form and strength, *we know biosimilars will infringe these method of use patents.* We have method of treatment patents covering all the indications for which HUMIRA has been approved. These patents do not expire until 2022 or later.
> . . .
> *Again, a biosimilar company will have to contend with our method of treatment patents for every indication for which it seeks approval, as well as our formulation and manufacturing patents which are not limited to any particular indication.*
> . . .
> *As you evaluate the timeframe for a potential U.S. biosimilar market entry, it is important that you consider the legal process and the likely timeline for resolution.* While it's always difficult to estimate the precise duration of the litigation process, the average time to trial for a patent action is nearly 3.5 years. Appeals to the Federal Circuit Court usually take one year. So, based on similar cases, the total litigation timing may be as long as four or five years. *At risk launches, when a company launches a generic product before patent expiration and before a final determination that a patent is invalid or not infringed, are relatively rare due to the potential exposure. Because of HUMIRA's success such damages could be extremely large.*
> . . .
> *However, in the event a biosimilar attempts to launch at risk, AbbVie will seek injunctive relief.* For the reasons we've already discussed, *biosimilars will necessarily infringe our patents.*

88. AbbVie repeatedly emphasized that its IP strategy relied on having many patents, not just a few. And to make things even more difficult, it would not describe the patents in detail or disclose its specific intentions regarding those patents. On AbbVie's earnings call on July 29, 2016, Mr. Gonzalez stated:

> Back in October, we outlined in detail the extensive portfolio of IP that we have for HUMIRA and our confidence in that IP and *it goes beyond any one single patent*. And I can tell you we remain confident in that IP portfolio and *we've made it very clear that we intend to vigorously defend all of our IP against anyone that potentially infringes it*. And, so that process will play out. So, as I said, *it's just not prudent for us now in this space to ultimately lay out in detail the play-by-play*. And so we're just not in a position to be able to do that.

89. AbbVie needed a huge volume of patents because it did not want to rely on the validity of any individual patent. And AbbVie was aware that it was likely to lose if it sought to

defend its patents from challenges. On AbbVie's earnings call on April 27, 2017, Mr. Gonzalez stated:

> [I]f you look at our level of confidence in what we've described to the market about our ability to protect Humira, it remains the same. *And that confidence was built around a large portfolio of IP; it was never contingent upon any one set of IP or any single set of patents or individual patents. . . .*
>
> Having said that, *if I look at the pure statistics around IPR decisions, I would say the statistics are against you, right?* More times than not, they're not upheld at an individual level.

90. As AbbVie openly acknowledges, its IP strategy is substantially the same now as it was in 2013. It has sought, and continues to seek, to delay biosimilar competition until many years after the 2016 expiration of the '382 patent by threatening, and sometimes filing, patent infringement litigation and promising crushing damages for any biosimilar that dares to launch at risk. On AbbVie's earnings call on October 27, 2017, Mr. Gonzalez stated:

> [W]e believe . . . that we will not see direct biosimilar competition in the U.S. until at least the 2022 timeframe. *Importantly, this will allow a number of key assets within our robust late-stage pipeline to enter the marketplace and establish a strong growth trajectory.*
> . . .
> [I]f you look at our objective when we launched the company, *we knew from day one that there was a point of time when we would be dealing with biosimilar competition on HUMIRA.* And our whole focus on building a pipeline, a robust pipeline, was designed to allow us to be able to grow through that period.
>
> *And we talked over and over again about the importance of the 2019 date in order to launch those products and ultimately be able to drive them up the growth curve to the point where they are profitable and they are contributing significantly.* And I think as we continue to advance, we are hitting all of those milestones that we set for ourselves to be able to do that. *And so I would tell you that our whole intent was to be able to drive through that erosion curve that we expected.*
> . . .
> And so I think what gives us confidence is we fundamentally believe, one, *[an at-risk launch is] an incredibly risky strategy for someone to take based on the size of this asset and the damage that would be done and the consequences of that damage if they lost.* Number two, I don't know that I can be any clearer about what our intent is, but *I think they understand what our intent would be to defend it.*

91. AbbVie's goal was not to protect its legitimate interests, but instead to create a thicket of patents that—regardless of their validity—could impede and deter potential competitors.

2. AbbVie's patent thicket consists of overlapping patents, drawn from just a few families, and largely from applications filed more than a decade after Humira launched.

92. There is no publicly-available catalogue of AbbVie's Humira-related patents,[45] but one analyst estimated that AbbVie has filed 247 patent applications and obtained 132 patents related to Humira, while noting that its methodology "likely undercounted" the "overall number of patent applications and granted patents[.]"

93. AbbVie obtained this enormous number of patents by filing a seemingly never-ending series of continuation applications of the Humira-related patent applications that Abbott had been prosecuting since it acquired BASF's adalimumab intellectual property in 2001. In general, the continuation applications are substantially similar to the parent applications with minor variations. Moreover, AbbVie frequently filed continuation applications just before patents issued so that it could keep alive the original application's priority date and seek even more duplicative patents.

94. AbbVie's conduct concerning a family of formulation patents illustrates how the scheme worked.

95. On August 16, 2002, Abbott filed U.S. Application No. 10/222,140 ("the '140 application"). The '140 application never resulted in a patent; Abbott abandoned the application in 2005. But the 2002 priority date of the '140 application was critical: Abbott began selling

[45] As noted above, unlike the Orange Book, the Purple Book does not require a biologic manufacturer to identify the patents covering its product.

Humira in 2003, and these sales would invalidate any formulation patent with a priority date more than a year later.[46] Abbott and later AbbVie went to great lengths to keep alive the 2002 priority date of the '140 application.

96. On August 15, 2003, before abandoning the '140 application, Abbott filed an international continuation patent application, PCT/IB2003/004502, now expired. On October 27, 2005, it filed a continuation of this international patent application, U.S. Application No. 10/525,292, a U.S. National Stage Application under 35 U.S.C. § 371. Abbott prosecuted this application for nearly seven years until it issued as U.S. Patent No. 8,216,583 on July 10, 2012. On May 15, 2012, shortly before the patent issued, Abbott filed another continuation application, U.S. Application No. 13/471,820, so that it could use the priority date of the '140 application to obtain more patents. The '820 application ultimately issued as U.S. Patent No. 8,932,591 on January 13, 2015, but before it did, AbbVie filed four more continuation applications. AbbVie employed this technique over and over again, filing new continuation applications shortly before new patents issued, so as to keep alive the 2002 priority date.

97. Altogether, the '140 application resulted in at least twenty-two patents, all of which were based on applications that, but-for the claimed priority to the '140 application, would have been barred, and all of which issued more than nine years after AbbVie began selling Humira. The specification of the 9,732,152 patent, issued August 15, 2017, provides a narrative of one chain of AbbVie's serial continuation applications. It reads, in part:

> This application *is a continuation* of U.S. patent application Ser. No. 15/095,393, filed Apr. 11, 2016, *which is a continuation* of U.S. patent application Ser. No. 14/826,357, filed Aug. 14, 2015, now U.S. Pat. No. 9,327,032, issued May 3, 2016, *which is a continuation* of U.S. patent application Ser. No. 14/558,182, filed Dec. 2, 2014, now U.S. Pat. No. 9,114,166, issued Aug. 25, 2015, *which is a continuation* of U.S. patent application Ser. No. 14/453,490, filed Aug. 6, 2014, now U.S. Pat.

[46] *See* 35 U.S.C. § 102.

No. 8,916,158, issued Dec. 23, 2014, *which is a continuation* of U.S. patent application Ser. No. 14/322,581, filed Jul. 2, 2014, now U.S. Pat. No. 8,911,741, issued Dec. 16, 2014, *which is continuation* of U.S. patent application Ser. No. 14/091,938, filed Nov. 27, 2013, now U.S. Pat. No. 8,795,670, issued Aug. 5, 2014, *which is a continuation* of U.S. patent application Ser. No. 13/471,820, filed May 15, 2012, now U.S. Pat. No. 8,932,591, issued Jan. 13, 2015, *which is a continuation* of U.S. patent application Ser. No. 10/525,292 filed Oct. 27, 2005, now U.S. Pat. No. 8,216,583, issued Jul. 10, 2012, which is a United States National Stage Application under 35 U.S.C. § 371 of PCT/IB2003/004502, filed Aug. 15, 2003 (now expired), *which is a continuation* of U.S. patent application Ser. No. 10/222,140, filed Aug. 16, 2002 (now abandoned).

98. AbbVie followed a similar approach with several other patent applications that date to the early 2000s.

99. Abbott filed a few patent applications shortly after it acquired rights to adalimumab, and AbbVie again used serial continuation applications to apply for hundreds of patents.

3. AbbVie sought to obtain patents regardless of their merits.

100. AbbVie focused more on the sheer number of patents and claims it could assemble than on the validity of the individual patents and claims. As a result, many of its patents do not withstand scrutiny.

a. Many of AbbVie's use patents are obvious in light of prior art.

101. The Patent Trial and Appeal Board (PTAB) instituted *inter partes* review proceedings on at least five of AbbVie's use patents and found three patents invalid due to obviousness: U.S. Patent No. 8,889,135; U.S. Patent No. 9,017,680; and U.S. Patent No. 9,073,987. The two other IPR proceedings, regarding U.S. Patent Nos. 9,090,689 and 9,067,992, were terminated by settlement after institution but before the PTAB reached a final decision. As demonstrated by the PTAB's decision to institute proceedings, the PTAB had already concluded that there was a reasonable likelihood that at least one of the claims in each patent was invalid,

and had AbbVie not settled with Sandoz, the PTAB would have held that all the claims of these two patents were invalid.

102. U.S. Patent No. 9,512,216 is no better than the patents for which the PTAB instituted IPRs. The '216 patent claims, generally, a method for treating plaque psoriasis with a dosing regimen of adalimumab. The earliest application to which it claims priority was filed on April 9, 2004. But by then, Humira had been approved and sold to treat rheumatoid arthritis for over a year, with the dosing regimen described in the '216 patent, and it was known in the art that rheumatoid arthritis and plaque psoriasis are both chronic autoimmune diseases that were often treated by the same drugs administered in the same or similar doses and dosing regimens.

103. U.S. Patent No. 9,187,559 is similarly deficient. The '559 patent claims a method for treating idiopathic inflammatory bowel disease in a human subject by administering a first dose of 160 mg of adalimumab and a second dose of 80 mg of adalimumab two weeks later. Once again, the earliest application to which it claims priority was filed on April 9, 2004. But Humira had been sold commercially to treat rheumatoid arthritis for over a year before this date, and a World Intellectual Property Organization publication on December 19, 2002, disclosed that a similar subcutaneous injection of adalimumab could treat idiopathic inflammatory bowel disease. The same WIPO reference also taught an 80 mg biweekly dosing regimen to treat rheumatoid arthritis and idiopathic inflammatory bowel disease, and a doubled initial dose was well known in the art at the time. The prior art demonstrates that the claims of this patent were obvious as of its priority date.[47]

[47] This prior art includes, but is not limited to, Goodman & Gilman's *The Pharmacological Basis Of Therapeutics,* 25-27 (Joel G. Hardman et al. eds., 10th ed. 2001); Physicians' Desk Reference, *Remicade entry* 1178-1182 (57th ed. 2003); Stephen B. Hanauer & Themistocles Dassopoulos, *Evolving Treatment Strategies for Inflammatory Bowel Disease,* 52 Annual Review Med. 299-318 (2001).

b. There is significant invalidating prior art for AbbVie's formulation patents.

104. AbbVie's formulation patents generally claim priority to the '140 application, filed on August 16, 2002.

105. The '382 patent discloses adalimumab (under its older name "D2E7") and describes incorporating adalimumab into pharmaceutical compositions, including liquid dosage forms that may comprise polyalcohols, buffers, or surfactants. The '382 patent issued on July 18, 2000, before the '140 application's filing date. As such, the '382 patent is invalidating prior art to all the formulation patents.

106. The '382 patent describes every element of the later formulation patents' claims except for the concentration of adalimumab, the type of surfactant, the concentration of surfactant, and, for some patents, the type of buffer. But each of these other elements are routine optimization that a skilled artisan could perform. And they were all easily discoverable in other prior art available in 2002, including publications by van de Putte,[48] Barrera,[49] Remington,[50] and others,[51] as well as United States Patent Nos. 6,171,586, issued January 9, 2001, and 6,252,055, issued June 26, 2001.

[48] B. A. van de Putte et al., *Efficacy of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis*, 42 Arthritis & Rheumatism (1999) (ACR Abstract Concurrent Session, RA: TNF-Blockade, Wednesday, Nov. 17, 1999 S400).

[49] P. Barrera et al., *Effects of Treatment with a Fully Human Anti-Tumour Necrosis Factor α Monoclonal Antibody on the Local and Systemic Homeostasis of Interleukin 1 and TNFα in Patients with Rheumatoid Arthritis*, 60 Annals Rheumatic Disease 660 (July 2001).

[50] Remington: *The Science and Practice of Pharmacy*, (Alfonso R. Gennaro ed., 20th ed. 2000).

[51] These include, but are not limited to, L.B.A. van de Putte et al., *Six Month Efficacy of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis*, 59 Annals of the Rheumatic Diseases Supp.1 (2000).

c. AbbVie made material misrepresentations and omissions to the PTO during the prosecution of its patents.

107. In 2006, AbbVie filed U.S. Provisional Application Nos. 60/845,158 and 60/876,374, followed by a series of continuation applications that issued as, among others, U.S. Patent Nos. 8,093,045, 8,911,964, and 9,090,867. These patents claim a fed batch method of producing a protein or various antibodies, including adalimumab. AbbVie had been using a substantially similar process since it began manufacturing and selling Humira in 2002. But AbbVie did not reveal that the process it was seeking to patent was not new, and was, in fact, embodied in its prior commercial sales. Instead, it concealed this information. In the prosecution of the '867 patent, the PTO observed that certain prior art[52] "teaches a generic high-yield fed batch method of making antibodies" and stated that "[a]pplicants are urged to provide any details they see as pertinent to the instant claims (e.g., 2 g/L antibody production, pH ramp, two different temperatures)." AbbVie argued in response that "none of the cited documents teach, suggest, or render obvious . . . a fed batch method for making an anti-TNFα antibody" but AbbVie did not disclose its prior use of the process to make a product that it had sold commercially for several years before the application's priority date.

108. Likewise, in the prosecution of the 9,018,361 patent, AbbVie misrepresented material information. This patent claims "[a] process for purifying adalimumab from a fermentation harvest of a Chinese Hamster Ovary (CHO) cell culture expressing said adalimumab," where the process comprises "a) binding adalimumab from said fermentation harvest to a Protein A resin, b) eluting the bound adalimumab at an elution pH of 3.6-4, and

[52] Y.H. Chang, *Abstracts of Papers of the American Chemical Society*, 219(1-2), pp. BIOT 171, print. Meeting Info.: 219th Meeting of the American Chemical Society. San Francisco, CA. March 26-30, 2000.

c) incubating the eluted adalimumab for 1 to 3 hours." As a continuation of U.S. Patent Application No. 12/582,506, which claims the benefit of U.S. Provisional Application No. 61/196,753, the patent's priority date is October 20, 2008. During prosecution, the PTO rejected the claims as obvious in light of U.S. Patent No. 5,429,746 and a publication of U.S. Patent No. 7,820,799. Although it does not specifically mention the adalimumab antibody itself, the '746 patent teaches nearly every step of the process claimed in the '361 patent, except those aspects that were routine optimization. And the '799 patent taught the use of Protein A chromatography for purifying adalimumab. The PTO concluded that the two prior art references together rendered the claims of the '361 patent obvious.

109. AbbVie responded with a declaration from Diane Dong, who affirmed under oath, among other things:

> [I]t is my opinion that it was unexpected that adalimumab could be successfully purified from CHO cells without significantly [sic] degradation, even with acidic elution of protein A resins followed by a substantial period of viral inactivation under low-pH conditions.

110. But three specific items of prior art made clear that the success of Protein A purification was not unexpected. First, the '382 patent disclosed that adalimumab "can be recovered from the culture medium using standard protein purification methods." This suggests that a standard method of purification, such as Protein A purification, would be effective for adalimumab.

111. Second, the prior art WO2007117490 publication—a publication of now-abandoned application 11/296,926—disclosed that "Protein A capture, in which an antibody-HCP mixture is applied to a protein A column such that the antibody binds to protein A and HCPs flow through, typically is used as an initial purification step in antibody purification

procedures as a means to remove HCPs." This makes clear that Protein A purification is a standard purification method for antibody purification.

112. Third, U.S. Patent No. 9,090,867—whose application was pending during the prosecution of the '361 patent—disclosed that "[i]t is also possible to utilize an affinity column comprising a polypeptide-binding polypeptide, such as a monoclonal antibody to the recombinant protein, to affinity-purify expressed polypeptides." One of the polypeptides discussed is adalimumab. The patent's specification adds that "[o]ther types of affinity purification steps can be a Protein A or a Protein G column, which affinity agents bind to proteins that contain Fc domains." This again suggests that Protein A purification would be effective for adalimumab. AbbVie did not disclose this application during the prosecution of the '361 patent.

113. These prior art references make clear that Protein A purification was known in the art, and it was a misrepresentation for Dr. Dong to claim that the process yielded unexpected results.

C. Amgen submits the first application for a Humira biosimilar and ultimately gets paid to delay entry by five years.

114. Beginning in 2015, pharmaceutical manufacturers—including some of the biggest pharmaceutical companies in the world—submitted ABLAs under 42 U.S.C. § 262(k) for approval to manufacture biosimilars to Humira. Amgen filed the first such application.

115. On November 25, 2015, Amgen submitted ABLA No. 761204 to the FDA seeking approval to market Amjevita, a biosimilar to Humira. The FDA accepted Amgen's ABLA on January 22, 2016.

116. On January 25, 2016, Amgen informed AbbVie that the FDA had accepted its ABLA for review. On February 10, 2016, Amgen provided AbbVie with a copy of its ABLA

under the confidentiality provisions set forth in 42 U.S.C. § 262(*l*)(1) of the BPCIA. On April 11, 2016, AbbVie identified, on its 3A list, 66 patents AbbVie contended that Amgen's biosimilar would infringe.

117. On June 10, 2016, Amgen responded with its 3B statement explaining in over 2,750 pages why 65 of the patents on AbbVie's 3A list are invalid and/or would not be infringed by Amgen's biosimilar Amjevita. Amgen supported its 3B statement with detailed claim charts, citations to the specifications of AbbVie's patents, and numerous prior art references. The lone patent for which Amgen did not contest validity or infringement was the '382 patent; instead, Amgen certified that it did not intend to begin commercial marketing of its biosimilar Amjevita before December 31, 2016, the date the '382 patent expired.

118. On June 21, 2016, a mere eleven days into its sixty-day period for responding, AbbVie sent its 3C response to Amgen. AbbVie provided no response at all to Amgen's contentions regarding six patents. For the other 59 patents, AbbVie responded in part but largely failed to address the Amgen's non-infringement assertions or to state the basis for any infringement assertions it might make. Despite having Amgen's ABLA, providing information on the composition of Amjevita and the uses for which Amgen sought approval, as well as manufacturing information for the drug, AbbVie repeatedly contended that it did not have sufficient information available to it to formulate an infringement theory. AbbVie did not ask for any additional information from Amgen, though, a step it presumably would have taken if it sought a good faith assessment of any potential infringement. AbbVie's 3C response also ignored many of Amgen's invalidity contentions and did not respond to Amgen's invalidity claim charts.

119. Amgen notified AbbVie on at least three separate occasions—June 24, 2016, July 1, 2016, and July 15, 2016—that AbbVie had not complied with paragraph 3(C) and provided a detailed list of deficiencies, including a specific list of the Amgen's non-infringement and invalidity contentions to which AbbVie had not responded.

120. AbbVie refused to remedy the deficiencies and instead stated its desire to assert 61 patents (covering more than 1,000 patent claims) in the litigation. Lacking AbbVie's bases for assertions of infringement of many of these claims, Amgen attempted to narrow the scope of the litigation, suggesting, for example, that the parties select a smaller number of patents and claims that presented unique issues of invalidity or infringement; AbbVie refused.

121. On July 30, 2016, Amgen informed AbbVie that it would identify six patents to be the subject of an infringement action (or at least the first phase of such an action); under the statute, this limited AbbVie to identifying six patents as well. On August 4, 2016, the parties exchanged their lists of patents, and AbbVie filed suit on all listed patents. AbbVie identified U.S. Patent Nos. 8,911,964; 8,916,157; 8,986,693; 8,961,973; 9,096,666; and 9,272,041. Amgen identified U.S. Patent Nos. 8,663,945; 8,986,693; 9,096,666; 9,220,781; 9,359,434; and 9,365,645. Because both parties identified the '693 and '666 patents, the total number of patents in suit was 10.

122. On September 23, 2016, the FDA granted approval of Amgen's biosimilar Amjevita. Amjevita is the fourth biosimilar ever approved by the FDA.

123. On November 17, 2016, the court set a schedule for discovery, briefing, and trial in the *AbbVie v. Amgen* matter. The schedule called for the close of fact discovery in January 2018, the close of expert discovery in May 2019, and trial in November 2019.

124. On September 28, 2017, many months before the close of fact discovery and without any substantive rulings, AbbVie and Amgen settled their litigation. Although the settlement is confidential, AbbVie's press release makes clear that the parties agreed that Amgen agreed to drop its patent challenges and not to enter the market for and compete with Humira until January 31, 2023, more than five years later. In exchange for this delay, even though it was the defendant in the litigation and had no claim to damages or other monetary relief, Amgen received a valuable exclusivity worth hundreds of millions of dollars.

125. Amgen was the first to file for FDA approval of a biosimilar to Humira but it was not the only one. Many other manufacturers have filed for FDA approval for their biosimilars, looking to compete with and take a piece of the market for Humira, the largest-selling drug in the United States for several years running. The FDA has approved at least two other biosimilars since approving Amgen's.

126. Unlike the Hatch-Waxman Act's framework that allows 180 days of exclusivity for the first generic, Amgen was not entitled to any period of exclusivity on the market to compete with Humira. The AbbVie-Amgen deal, though, gave Amgen precisely that. AbbVie agreed not to settle with any other manufacturers on terms that would let them enter the market at the same time as Amgen, or for five months thereafter, thus ensuring that Amgen would not have to compete with any other biosimilars to Humira for the first five months it is on the market. All biosimilar sales—and thus all biosimilar profits—during those five months will go into Amgen's pocket.

127. Such a period of exclusivity is highly valuable. In 2018, revenues from Humira U.S. sales were $13.7 billion. Had one or more biosimilars been in the market then, they would have taken a significant portion of those revenues for themselves. Even if biosimilars captured

only 20% of the market with price reductions of 20% (both conservative figures used here for emphasis only), biosimilar revenues would have been $2.2 billion in 2018 or $913 million for five months.

128. Instead of splitting those revenues among multiple biosimilar competitors, AbbVie and Amgen's agreement makes sure that Amgen can monopolize the Humira biosimilar market for five months. Assuming that Amgen and another biosimilar competitor would have evenly split the biosimilar market, Amgen could have expected $456.5 million in revenues in five months of exclusivity in 2018; as a result of the deal, however, the entire $913 million would have been allocated to Amgen. In short, the exclusivity period AbbVie used to pay Amgen to delay entry is worth hundreds of millions of dollars at 2018 levels of Humira sales. Depending on the growth of Humira until 2023, Amgen's payment for waiting to launch may be worth significantly more.

129. Both AbbVie, by extending its Humira monopoly, and Amgen, by gaining hundreds of millions of dollars in expected revenue as a result of the de facto exclusivity period it received, benefit greatly from their reverse payment agreement. But while AbbVie and Amgen win, payers are the big losers in the deal, forced to continue paying supra-competitive prices for Humira for many more years without competition and then denied the benefits of competition between biosimilars during Amgen's five-month exclusivity period.

D. AbbVie enters into deals with other would-be competitors, delaying their entry and preserving the five-month payment to Amgen.

1. AbbVie next settles with Samsung Bioepis despite there being no litigation between the companies.

130. On April 5, 2018, AbbVie and Samsung Bioepis announced a "global resolution of all intellectual property-related litigation with Samsung Bioepis over its proposed biosimilar adalimumab product." AbbVie secured this deal with Samsung Bioepis three months before

Samsung Bioepis even filed an application with the FDA for approval of a biosimilar to Humira and thus before any U.S. patent assessment occurred or litigation commenced.

131. The deal allows Samsung Bioepis to begin marketing its adalimumab product in the European Union on October 16, 2018 but not until June 30, 2023 in the United States, five months after the date of Amgen's agreed entry. AbbVie's press release notes that the deal with Samsung Bioepis does not include an acceleration clause, meaning Samsung Bioepis cannot enter the market earlier if Amgen or any other Humira biosimilar enters before it.

132. In July 2018, three months after securing the deal, Samsung Bioepis submitted an ABLA for SB5, its Humira biosimilar. The FDA accepted it for review on September 27, 2018 and it remains pending.

2. The third would-be biosimilar to settle receives the third earliest entry date.

133. In or around early 2018, Mylan submitted an ABLA for Hulio, a biosimilar to Humira. On July 17, 2018, AbbVie announced a deal with Mylan, allowing Mylan to enter the U.S. market on July 31, 2023, six months after Amgen, the first to settle, and one month after Samsung Bioepis, the second to settle. Like the Samsung Bioepis deal, Mylan's U.S. launch date will not be accelerated by entry of other biosimilars.

3. AbbVie next settles with Sandoz and gives it the next entry date.

134. On January 16, 2018, the FDA accepted Sandoz's ABLA for Hyrimoz, a biosimilar to Humira, and on January 17, 2018, Sandoz commenced the pre-litigation exchanges provided for in the BPCIA by sharing its ABLA, which describes the formulation of its biosimilar Hyrimoz, with AbbVie.

135. On March 18, 2018, AbbVie provided Sandoz its 3A list, which described patents for which AbbVie asserted that it believed a claim of patent infringement could be reasonably

asserted. AbbVie supplemented that list on April 24, 2018, and May 1, 2018, each time adding a recently issued patent.

136. On May 16, 2018, Sandoz responded with its 3B statement, describing in detail why it believed that each patent identified by AbbVie was invalid or would not be infringed by its biosimilar.

137. On July 15, 2018, AbbVie provided Sandoz with its 3C statement. AbbVie's 3C statement identified 84 patents that it asserted would be infringed by Sandoz's biosimilar.

138. On August 5, 2018, Sandoz stated that it would identify one patent to be the subject of an infringement action, which limited AbbVie to identifying one patent as well.

139. On August 10, 2018, the parties exchanged their (*l*)(5) lists of patents. The parties identified U.S. Patent Nos. 9,187,559 and 9,750,808. Later the same day, AbbVie filed suit on both listed patents.

140. Despite having Sandoz's ABLA and manufacturing data and thus knowing the formulation for Hyrimoz, AbbVie unfairly and deceptively included in the patent dance patents for which there was not even an arguable claim of infringement by Hyrimoz. For example, nine of the formulation patents AbbVie included specify the use of a buffer system with a particular ingredient:

U.S. Patent No.	Claims a buffer system comprising
8,795,670	Histidine
8,802,101	Acetate
8,802,102	Succinate
8,940,305	Gluconate
9,272,041	Acetate
9,295,725	Succinate
9,327,032	Histidine
9,732,152	Histidine
9,738,714	Succinate

141. None of the ingredients identified in the table above is in Sandoz's biosimilar. (They are not even in Humira.) Nonetheless, even though the BPCIA requires that the brand manufacturer list only those patents for which "a claim of patent infringement could reasonably be asserted," AbbVie asserted in its 3C statement that Sandoz would infringe all nine of these patents.

142. Additionally, one of the two patents in suit claimed buffer systems not present in Hyrimoz. Claims 3, 19, 21, 23, 25, and 26 claim a formulation with a buffer system comprising succinate, acetate, or histidine, none of which are in Hyrimoz (or Humira). Nonetheless, AbbVie's complaint alleged that Sandoz's biosimilar infringed, among others, claims 3, 25, and 26.

143. On October 11, 2018, just two months after AbbVie filed suit against Sandoz regarding the two patents, before Sandoz responded to AbbVie's complaint, and without any litigation on the other 82 patents AbbVie claimed were infringed, AbbVie and Sandoz announced a deal to allow Sandoz's biosimilar to enter the U.S. market on September 30, 2023, eight months after Amgen. The deal, like others, has no acceleration clause. Sandoz could launch in the European Union, however, on October 16, 2018.

144. On October 31, 2018, the FDA approved Hyrimoz.

4. Fresenius Kabi settles on the heels of Sandoz and gets the same entry date without even filing a biosimilar application in the United States.

145. On December 19, 2017, Fresenius Kabi announced that it had submitted a Marketing Authorization Application for MSB11022, a biosimilar to Humira to the European Medicines Agency (EMA) and that the EMA had accepted it for review. There is no indication that Fresenius Kabi filed an ABLA with the FDA or engaged in the patent dance with AbbVie and AbbVie did not sue Fresenius Kabi in the United States.

146. Yet, on October 18, 2018, AbbVie and Fresenius Kabi announced a "global resolution of all intellectual property-related litigation" related to MSB11022, delaying U.S. entry of Fresenius Kabi's biosimilar until September 30, 2023, the same day Sandoz is allowed to enter. Like the deals before it, the AbbVie-Fresenius Kabi deal does not include an acceleration clause for U.S. market entry. In the European Union, Fresenius Kabi can enter as soon as the EMA issues approval.

5. AbbVie enters a deal with Momenta without litigation, allowing it the fifth entry date.

147. In May 2018, Momenta announced its intention to submit an ABLA for M923, a biosimilar of Humira, after "business development discussions." On October 1, 2018, Momenta announced that it had completed these discussions. On November 6, 2018, AbbVie and Momenta announced a deal allowing Momenta to begin marketing its Humira biosimilar in the United States (and thus competing with Humira and other biosimilars) on November 20, 2023, approximately ten months after Amgen's agreed entry, five months after Samsung Bioepis's agreed entry, four months after Mylan's agreed entry, and two months after Sandoz and Fresenius Kabi's agreed entry. The deal contains no acceleration clause.

6. AbbVie makes its next deal with Pfizer in a matter of weeks, allowing it to enter with Momenta.

148. On August 20, 2018, Pfizer announced positive results from its Phase 3 trials of PF-06410293, a biosimilar of Humira. Three months later, on November 30, 2018, AbbVie and Pfizer announced "a global resolution of all intellectual property-related litigation concerning Pfizer's proposed biosimilar adalimumab." The deal allows Pfizer to enter on November 20, 2023, the same date as Momenta, in the United States and upon EMA approval in the European Union. As with AbbVie's other deals, the agreement with Pfizer contains no acceleration clause.

7. AbbVie gives Coherus, as last to settle (so far), the latest entry date.

149. Between 2015 and 2017, Coherus filed a number of petitions for *inter partes* review of Humira-related patents. On January 25, 2019, Coherus announced a global settlement resolving "all pending disputes between [Coherus and AbbVie] related to Coherus' adalimumab biosimilar." Under the terms of the deal, Coherus can begin marketing its Humira biosimilar on December 15, 2023.

8. One biosimilar manufacturer remains in litigation with AbbVie, challenging the patent thicket: Boehringer.

150. On October 27, 2016, Boehringer submitted ABLA No. 761058 for Cyltezo, a biosimilar to Humira. On January 9, 2017, the FDA accepted Boehringer's ABLA. Four days later consistent with the statutorily-required disclosures, Boehringer provided AbbVie with 93,750 pages relating to ABLA 761058.

151. On March 13, 2017, AbbVie, in its 3A statement, identified 72 patents it argued would be infringed by Boehringer's adalimumab biosimilar, including the '382 patent that expired more than two months earlier, on December 31, 2016. AbbVie subsequently added three more patents to its 3A list.

152. On May 12, 2017, Boehringer provided AbbVie with 1,841 pages describing in detail the bases for non-infringement and invalidity of 73 patents identified by AbbVie (and provided details on the bases for non-infringement and invalidity for the two later added patents in July 2017.

153. On July 11, 2017, AbbVie responded, alleging infringement and validity of 71 of the 72 patents (omitting only the expired '382 patent from its contentions), and including multiple patents that had been invalidated by the PTAB. On July 21, 2017, Boehringer requested that AbbVie remove from the patent dance at least 16 patents that it had asserted for which

AbbVie admitted it lacked any evidence to allege infringement; AbbVie declined, claiming it needed additional, but unspecified, information. (AbbVie did not then request any such information.)

154. Boehringer stated that it would identify five patents to be the subject of an infringement action; this limited AbbVie to identifying five patents as well. On July 31, 2017, the parties exchanged their lists of patents. AbbVie identified U.S. Patent Nos. 8,926,975; 9,018,361; 9,266,949; 9,272,041; and 9,546,212. Boehringer identified U.S. Patent Nos. 8,926,975; 9,090,867; 9,096,666; 9,255,143; and 9,272,041. AbbVie filed suit on all listed patents on August 2, 2017. Because both parties identified the ’975 and ’041 patents, the total number of patents in suit was eight.

155. On August 28, 2017, the FDA approved Boehringer’s biosimilar. The Boehringer suit is still pending.

156. Boehringer asserted in its counterclaims that AbbVie has “engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a ‘patent thicket,’ using the patenting process itself as a means to seek to delay competition against its expensive and lucrative adalimumab product. That strategy has generated . . . more than 100 patents.” For example, “all 74 patents [in AbbVie’s 3A list] . . . were issued between 2012 and 2017” and “stem from less than half as many patent families. Many of the patents identified by [AbbVie] share common specifications and have overlapping and nearly identical claims.”

E. AbbVie’s deals are having their intended effect: delaying competition for Humira and lower prices for payers.

157. Eight of nine would-be competitors to AbbVie for Humira have agreed not to launch their biosimilars until 2023. AbbVie paid the first to settle—Amgen—with five months as

the exclusive Humira biosimilar on the market. All other entrants are staggered: the later the deal, the later the agreed entry date.

Company	Settlement/Agreement Date	Agreed Entry Date	Biosimilar Approved
Amgen	September 28, 2017	January 31, 2023	September 23, 2016
Samsung Bioepis	April 5, 2018	June 30, 2023	
Mylan	July 17, 2018	July 31, 2023	
Sandoz	October 11, 2018	September 30, 2023	October 31, 2018
Fresenius Kabi	October 17, 2018	September 30, 2023	
Momenta	November 6, 2018	November 20, 2023	
Pfizer	November 30, 2018	November 20, 2023	
Coherus	January 25, 2019	December 15, 2023	
Boehringer Ingelheim	N/A	N/A	August 28, 2017

158. Three biosimilars have been approved and, but for AbbVie's anticompetitive conduct, would be able to launch.

VI. CLASS ALLEGATIONS

159. Plaintiff SPEW brings this action under Federal Rules of Civil Procedure 23(a) and (b)(2) as a representative of a class seeking injunctive relief ("Injunctive Relief Class") defined as follows:

> All entities in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Humira, other than for resale, from December 31, 2016, through the present.

160. Plaintiff also brings this action under Federal Rules of Civil Procedure 23(a) and (b)(3) as a representative of a class seeking damages ("Damages Class") defined as follows:

> All entities who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Humira, other than for resale, in Arizona, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin from December 31, 2016, through the present, for consumption by their members, employees, insureds, participants, or beneficiaries.

161. The following persons and entities are excluded from the Injunctive Relief Class and the Damages Class (together, the "classes"):

a. Natural persons;

b. AbbVie and its subsidiaries and affiliates;

c. All federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;

d. All entities who purchased Humira for purposes of resale or directly from AbbVie or its affiliates;

e. Fully insured health plans, i.e., plans that purchased insurance covering 100% of their reimbursement obligation to members; and

f. Pharmacy benefit managers.[53]

162. The members of each class are so numerous that joinder is impracticable. Each class includes at least thousands of members. Members of the classes are widely dispersed throughout the country.

163. Plaintiff's claims are typical of the claims of all class members. Plaintiff's claims arise out of the same common course of conduct that gives rise to the claims of the other class members. Plaintiff and all class members were and will continue to be damaged by the same wrongful conduct, *i.e.*, they paid and will continue to pay artificially inflated prices for Humira and were and continue to be deprived of the benefits of competition as a result of AbbVie and Amgen's conduct.

164. Plaintiff will fairly and adequately protect and represent the interests of the classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the classes.

[53] Pharmacy benefit managers do not fit within the class definition as they do not purchase, pay, and/or provide reimbursement, and are included in the list of exclusions for the avoidance of doubt.

165. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation and have particular expertise with class action antitrust litigation in the pharmaceutical industry.

166. Questions of law and fact common to the classes include:

a. Whether AbbVie and Amgen's agreement constitutes a violation of the state laws listed below;

b. Whether AbbVie and Amgen conspired to restrain biosimilar competition to Humira;

c. Whether there were legitimate procompetitive justifications explaining AbbVie and Amgen's agreement;

d. Whether AbbVie's conduct was unfair and/or unconscionable in violation of the state laws listed below;

e. Whether AbbVie possessed market power in the relevant market;

f. To the extent a relevant market must be defined, what that definition is; and

g. The quantum of aggregate overcharge damages paid by the Damages Class.

167. Questions of law and facts common to the Damages Class members predominate over any questions that may affect only individual class members, because AbbVie and Amgen have acted on grounds generally applicable to the entire Damages Class.

168. Class treatment is a superior method for the fair and efficient adjudication of the controversy because, among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a similar forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that

might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

169. Class treatment also is appropriate under Rule 23(b)(2). The prosecution of separate actions by individual members of the Injunctive Relief Class would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for AbbVie and Amgen. In addition, the prosecution of separate actions by individual members of the Injunctive Relief Class would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other class members not parties to such adjudications or would substantially impair or impede other class members' ability to protect their interests. Lastly, AbbVie and Amgen have acted and refused to act on grounds that apply generally to the Injunctive Relief Class such that final injunctive relief and/or declaratory relief is warranted with respect to the class as a whole.

170. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND RELEVANT MARKET

171. The relevant geographic market is the United States and its territories and possessions.

172. Direct evidence demonstrates AbbVie's market power. It shows that (1) but for the anticompetitive conduct alleged above, biosimilar versions of Humira would have entered the market at substantially lower prices than Humira; (2) AbbVie maintained and raised the price of Humira despite the presence of other drugs on the market; and (3) AbbVie never lowered Humira prices or lost sales volume in response to the pricing of other drugs. Humira is the best-selling product in the world, indicating that its sales are not constrained by any other products.

173. To the extent Plaintiff is required to show market power indirectly, the relevant

product market is the sale of adalimumab and has consisted solely of Humira. Biosimilar versions of Humira will also be in the relevant market once they are available. At all relevant times, AbbVie's share of the relevant adalimumab market was and remains 100%.

174. Biologic drugs like Humira are differentiated from other drugs based on features and benefits (including safety and efficacy), and not only based upon price. Doctors and patients are generally price-insensitive when prescribing and purchasing prescription drugs like Humira, in part because insurers typically bear much of the cost of prescriptions. Even drugs within its same therapeutic class do not constrain the price of Humira.

175. Humira is not reasonably interchangeable with any products apart from biosimilar versions of Humira. Other products are not practical substitutes for Humira.

176. At all relevant times, potential entrants into the market for adalimumab faced high barriers to entry due, in large part, to the lengthy and complex process of maintaining FDA approval and AbbVie's patent thicket.

177. Humira does not exhibit significant, positive cross-price elasticity of demand with any other medication. The existence of non-adalimumab products that may be used to treat similar indications as Humira did not constrain AbbVie's ability to raise or maintain Humira prices without losing substantial sales, and therefore those other drug products do not occupy the same relevant antitrust market as Humira.

178. AbbVie needed to control only Humira, and no other products, to maintain profitably and maintain a supra-competitive price for Humira while preserving all or virtually all of its sales. Only market entry of a competing, biosimilar version of Humira would render AbbVie unable to profitably maintain its Humira prices without losing substantial sales.

VIII. MARKET EFFECTS AND CLASS DAMAGES

179. But for the anticompetitive conduct alleged above, multiple manufacturers would have entered the market with biosimilars of Humira starting as early as December 31, 2016.

180. Instead, AbbVie willfully and unlawfully maintained its monopoly power in the market for adalimumab through a scheme to exclude competition. The scheme forestalled competition by biosimilars and brought about the anticompetitive effect of maintaining supra-competitive prices for Humira. AbbVie implemented its scheme by entering into an unlawful agreement with Amgen and creating a patent thicket intended to frustrate competitors' efforts to bring biosimilar version of Humira to the market. These acts, individually and in combination, were anticompetitive.

181. Three biosimilar manufacturers have received FDA approval, and the only impediments to them launching their biosimilar versions of Humira have been AbbVie and Amgen's unlawful agreement and AbbVie's patent thicket.

182. AbbVie's scheme—including its agreement with Amgen—had the purpose and effect of preventing biosimilar competition, permitting AbbVie to maintain supra-competitive monopoly prices for Humira, and enabling AbbVie to sell Humira without competition. Absent AbbVie and Amgen's conduct, biosimilar versions of Humira would have been available sooner.

183. Competition among drug manufacturers enables all purchasers of the drug to buy biosimilar equivalents of a drug at substantially lower prices or to buy the reference biologic product at reduced prices. Consequently, reference biologic manufacturers have a strong incentive to delay biosimilar competition, and purchasers experience substantial cost inflation from that delay.

184. If competition from biosimilar manufacturers had not been restrained and forestalled, end-payers like Plaintiff would have paid less for adalimumab by (a) purchasing, and

providing reimbursement for, biosimilar versions of Humira instead of more-expensive Humira and (b) purchasing, and providing reimbursement for, Humira at lower prices.

185. As a result, AbbVie and Amgen's conduct has caused and will continue to cause Plaintiff and the classes to pay more than they would have paid for Humira and biosimilar Humira absent that conduct.

IX. ANTITRUST IMPACT

186. The effect of AbbVie and Amgen's conduct was to net AbbVie billions of dollars in revenue at the expense of end-payers, including Plaintiff and the proposed classes, who paid hundreds of millions, if not billions, of dollars in unlawful overcharges.

187. During the relevant period, Plaintiff and class members purchased substantial amounts of Humira indirectly from AbbVie.

188. As a direct and proximate result of AbbVie and Amgen's unlawful conduct, Plaintiff and class members paid supra-competitive prices for Humira that were substantially higher than the prices they would have paid absent defendants' conduct because they were deprived of the opportunity to purchase lower-priced biosimilar versions of Humira.

189. As a result, Plaintiff and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

190. The overcharges resulting from AbbVie and Amgen's conduct are directly traceable through the pharmaceutical distribution chain to Plaintiff and other end-payers. A manufacturer first sells the drug to direct purchaser wholesalers based on the listed WAC, minus applicable discounts. Wholesalers then sell the drug to pharmacies, which in turn sell the drugs to consumers. In this short chain of distribution, drug products are not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies,

pharmacy benefit managers, and third-party payers (such as insurers and health and welfare funds). The products and their prices are thus directly traceable from the manufacturer until they reach the hands of the consumer at a pharmacy.

X. INTERSTATE AND INTRASTATE COMMERCE

191. AbbVie's and Amgen's efforts to restrain and forestall competition for Humira have substantially affected interstate commerce.

192. At all material times, AbbVie manufactured, marketed, promoted, distributed, and sold substantial amounts of Humira in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

193. At all material times, AbbVie transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Humira.

194. In furtherance of its efforts to restrain and forestall competition in the relevant market, AbbVie employed the U.S. mails and interstate and international phone lines, as well as means of interstate and international travel. AbbVie and Amgen's activities were within the flow of and have substantially affected interstate commerce.

195. AbbVie and Amgen's conduct also had substantial intrastate effects in that, among other things, retailers within each state were prevented from offering more affordable biosimilar Humira to end-payers inside each state. AbbVie and Amgen's conduct materially deprived the consuming public—including hundreds, if not thousands, of end-payers in each state—of any choice to purchase more affordable biosimilar Humira. The continued absence of competition to Humira directly and substantially affects and disrupts commerce within each state.

XI. CLAIMS FOR RELIEF

COUNT I: Violation of Section 1 of the Sherman Act (and Minn. Stat. §§ 325F.68-70 with respect to purchases in Minnesota by members of the Class): Pay-For-Delay Agreement (Against AbbVie and Amgen on Behalf of the Injunctive Relief Class)

196. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

197. AbbVie granted Amgen a period of exclusivity that it was not entitled to and was worth hundreds of millions of dollars. In exchange for this substantial consideration, Amgen agreed to drop its patent challenges and not to launch its FDA-approved biosimilar to compete with Humira until January 31, 2023.

198. AbbVie and Amgen's settlement is an unlawful pay-for-delay agreement and an illegal contract, combination, and conspiracy in restraint of trade. The purposes and effects of this agreement were to: (a) delay and prevent the entry of more affordable biosimilar versions of Humira in the United States; (b) fix, raise, maintain, or stabilize the prices of Humira; and (c) allocate 100% of the U.S. adalimumab market to AbbVie.

199. AbbVie and Amgen implemented the terms of the agreement, and it achieved its intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, alleged herein, Plaintiff suffered harm in the form of overcharges.

200. There was and is no legitimate, non-pretextual, procompetitive justification for the reverse payment from AbbVie to Amgen that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve that purpose.

201. Plaintiff and members of the Injunctive Relief Class will continue to suffer injury, in the form of overcharges paid for Humira, if AbbVie and Amgen's unlawful conduct is not enjoined.

202. Plaintiff and the members of the Injunctive Relief Class therefore seek equitable and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable laws, to correct for the anticompetitive market effects caused by AbbVie and Amgen's unlawful conduct, and to assure that similar anticompetitive conduct and effects do not continue or reoccur in the future.

203. Plaintiff and the members of the Injunctive Relief Class (Minnesota only) therefore seek equitable and injunctive relief under Minn. Stat. §§ 325F.68-70 with respect to purchases in Minnesota by members of the Class.

COUNT II: Violation of State Law: Pay-For-Delay Agreement
(Against AbbVie and Amgen on Behalf of the Damages Class)

204. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

205. AbbVie granted Amgen a period of exclusivity that it was otherwise not entitled to and was worth hundreds of millions of dollars. In exchange for this substantial consideration, Amgen agreed to drop its patent challenges and not to launch its FDA-approved biosimilar to compete with Humira until January 31, 2023.

206. AbbVie and Amgen's settlement is an unlawful pay-for-delay agreement and an illegal contract, combination, and conspiracy in restraint of trade. The purposes and effects of this agreement were to: (a) delay and prevent the entry of more affordable biosimilar versions of Humira in the United States; (b) fix, raise, maintain, or stabilize the prices of Humira; and (c) allocate 100% of the U.S. adalimumab market to AbbVie.

207. AbbVie and Amgen implemented the terms of the agreement, and it achieved its intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, alleged herein, Plaintiff suffered harm in the form of overcharges.

208. There was and is no legitimate, non-pretextual, procompetitive justification for the reverse payment from AbbVie to Amgen that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve that purpose.

209. AbbVie and Amgen's pay-for-delay agreement violates the following state antitrust laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1400, *et seq.*, with respect to purchases in Arizona by Damages Class members and/or purchases by Arizona residents.

b. Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and California common law with respect to purchases in California by Damages Class members and/or purchases by California residents.

c. C.G.S.A. §§ 35-26 and 28, *et seq.*, with respect to purchases in Connecticut by Damages Class members and/or purchases by Connecticut residents.

d. D.C. Code §§ 28-4502, *et seq.*, with respect to purchases in D.C. by Damages Class members and/or purchases by D.C. residents.

e. Haw. Rev. Stat. §§ 480-2, 480-4, *et seq.*, with respect to purchases in Hawaii by Damages Class members and/or purchases by Hawaii residents.

f. 740 Ill. Comp. Stat. §§ 10/3, *et seq.*, with respect to purchases in Illinois by Damages Class members and/or purchases by Illinois residents.

g. Iowa Code §§ 553.4, *et seq.*, with respect to purchases in Iowa by Damages Class members and/or purchases by Iowa residents.

h. Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to purchases in Kansas by Damages Class members and/or purchases by Kansas residents.

i. Me. Rev. Stat. Ann. 10 §§ 1101, *et seq.*, with respect to purchases in Maine by Damages Class members and/or purchases by Maine residents.

j. MD Code Ann., Com. Law, §§ 11-204, *et seq.*, with respect to purchases in Maryland by Damages Class members and/or purchases by Maryland residents.

k. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by Damages Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325D.51, *et seq.*, and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by Damages Class members and/or purchases by Minnesota residents.

m. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by Damages Class members and/or purchases by Mississippi residents.

n. Neb. Rev. Stat. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by Damages Class members and/or purchases by Nebraska residents.

o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by Damages Class members and/or purchases by Nevada residents.

p. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases in New Hampshire by Damages Class members and/or purchases by New Hampshire residents.

q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by Damages Class members and/or purchases by New Mexico residents.

r. N.Y. Gen. Bus. Law § 340 with respect to purchases in New York by Damages Class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by Damages Class members and/or purchases by North Carolina residents.

t. N.D. Cent. Code Ann. §§ 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by Damages Class members and/or purchases by North Dakota residents.

u. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases in Oregon by Damages Class members and/or purchases by Oregon residents.

v. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases in Rhode Island by Damages Class members and/or purchases by Rhode Island residents.

w. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by Damages Class members and/or purchases by South Dakota residents.

x. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by Damages Class members and/or purchases by Tennessee residents.

y. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases by Utah residents in the Damages Class.

z. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by Damages Class members and/or purchases by West Virginia residents.

aa. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by Damages Class members and/or purchases by Wisconsin residents.

210. AbbVie and Amgen's pay-for-delay agreement also violates the following state consumer protection laws that prohibit anticompetitive conduct:

a. Alaska Stat. Ann. § 45.50.471 with respect to purchases in Alaska by Damages Class members and/or purchases by Alaska residents. AbbVie and Amgen's pay-for-delay agreement is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by Damages Class members and/or purchases by California residents.

c. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by Damages Class members and/or purchases by Florida residents.

d. Ga. Code Ann. § 10-1-393 with respect to purchases in Georgia by Damages Class members and/or purchases by Georgia residents. AbbVie and Amgen's pay-for-delay agreement is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

e. S.C. Code Ann. § 39-5-20, *et seq.*, with respect to purchases in South Carolina by Damages Class members and/or purchases by South Carolina residents. AbbVie and Amgen's pay-for-delay agreement is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce. It is also offensive to public policy and immoral, unethical, and oppressive.

f. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by Damages Class members and/or purchases by Vermont residents. AbbVie and

Amgen's pay-for-delay agreement is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

211. Plaintiff and Damages Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Damages Class members (i) were denied the ability to purchase lower-priced biosimilar versions of Humira, and (ii) paid higher prices for Humira than they would have paid but for the unlawful conduct. These injuries are of the type that the above laws were designed to prevent, and flow from that which makes the conduct unlawful.

212. Plaintiff and Damages Class members accordingly seek damages and multiple damages as permitted by law.

COUNT III: Violation of State Law: Monopolization
(Against AbbVie on Behalf of the Damages Class)

213. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

214. During all relevant times, AbbVie has possessed market power in the relevant market. No other manufacturer sold a competing biosimilar version of Humira in the United States.

215. AbbVie's development, acquisition, and enforcement of its patent thicket was undertaken and executed without regard to the merits of the patents. It was not undertaken and executed in furtherance of legitimate uses of the patent system or out of a genuine interest in redressing grievances. AbbVie's conduct was instead intended solely to restrain trade, harass potential competitors, and perpetuate AbbVie's monopoly in the relevant market.

216. Through its anticompetitive conduct, AbbVie intentionally and willfully maintained monopoly power in the relevant market.

217. AbbVie's monopolistic conduct violates the following state antitrust laws:

a. Ariz. Rev. Stat. Ann. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by Damages Class members and/or purchases by Arizona residents.

b. C.G.S.A. §§ 35-27, *et seq.*, with respect to purchases in Connecticut by Damages Class members and/or purchases by Connecticut residents.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in D.C. by Damages Class members and/or purchases by D.C. residents.

d. Haw. Rev. Stat. §§ 480-2, 480-9, *et seq.*, with respect to purchases in Hawaii by Damages Class members and/or purchases by Hawaii residents.

e. 740 Ill. Comp. Stat. §§ 10/3, *et seq.*, with respect to purchases in Illinois by Damages Class members and/or purchases by Illinois residents.

f. Iowa Code §§ 553.5, *et seq.*, with respect to purchases in Iowa by Damages Class members and/or purchases by Iowa residents.

g. Me. Rev. Stat. Ann. 10 §§ 1102, *et seq.*, with respect to purchases in Maine by Damages Class members and/or purchases by consumer Maine residents.

h. MD Code Ann., Com. Law, §§ 11-204, *et seq.*, with respect to purchases in Maryland by Damages Class members and/or purchases by Maryland residents.

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by Damages Class members and/or purchases by Michigan residents.

j. Minn. Stat. §§ 325D.52, *et seq.* and Minn. Stat. §§ 8.31, *et seq.*, with respect to purchases in Minnesota by Damages Class members and/or purchases by Minnesota residents.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by Damages Class members and/or purchases by Mississippi residents.

l. Neb. Rev. Stat. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by Damages Class members and/or purchases by Nebraska residents.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by Damages Class members and/or purchases by Nevada residents.

n. N.H. Rev. Stat. Ann. §§ 356:3, *et seq.*, with respect to purchases in New Hampshire by Damages Class members and/or purchases by New Hampshire residents.

o. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by Damages Class members and/or purchases by New Mexico residents.

p. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by Damages Class members and/or purchases by North Carolina residents.

q. N.D. Cent. Code Ann. §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by Damages Class members and/or purchases by North Dakota residents.

r. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases in Oregon by Damages Class members and/or purchases by Oregon residents.

s. R.I. Gen. Laws §§ 6-36-5, *et seq.*, with respect to purchases in Rhode Island by Damages Class members and/or purchases by Rhode Island residents.

t. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by Damages Class members and/or purchases by South Dakota residents.

u. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases by Utah residents.

v. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by Damages Class members and/or purchases by West Virginia residents.

w. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by Damages Class members and/or purchases by Wisconsin residents.

218. AbbVie's conduct also violates the following state consumer protection laws that prohibit monopolization:

a. Alaska Stat. Ann. § 45.50.471 with respect to purchases in Alaska by Damages Class members and/or purchases by Alaska residents. AbbVie's monopolistic conduct is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by Damages Class members and/or purchases by California residents.

c. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by Damages Class members and/or purchases by Florida residents.

d. Ga. Code Ann. § 10-1-393 with respect to purchases in Georgia by Damages Class members and/or purchases by Georgia residents. AbbVie's monopolistic

conduct is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

e. S.C. Code Ann. § 39-5-20, *et seq.*, with respect to purchases in South Carolina by Damages Class members and/or purchases by South Carolina residents. AbbVie's monopolistic conduct is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce. It is also offensive to public policy and immoral, unethical, and oppressive.

f. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by Damages Class members and/or purchases by Vermont residents. AbbVie and Amgen's pay-for-delay agreement is an unfair method of competition and an unfair practice occurring in the conduct of trade and commerce.

219. Plaintiff and Damages Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Damages Class members (i) were denied the ability to purchase lower-priced biosimilar versions of Humira, and (ii) paid higher prices for Humira than they would have paid but for the unlawful conduct. These injuries are of the type that the above laws were designed to prevent, and flow from that which makes the conduct unlawful.

220. Plaintiff and Damages Class members accordingly seek damages and multiple damages as permitted by law.

COUNT IV: Violation of State Law: Unfair and Unconscionable Conduct (Against Defendant AbbVie on Behalf of the Damages Class)

221. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations

222. AbbVie engaged in unfair methods of competition and unfair and unconscionable acts and practices to wrongfully frustrate the process of biosimilar versions of Humira coming to market. AbbVie abused the regulatory and judicial system with its conduct was not intended to redress legitimate grievances but was instead undertaken for purposes of harassing would-be manufacturers.

223. AbbVie's conduct has offended public policy. The Biologics Price Competition and Innovation Act of 2009 established the abbreviated biosimilar approval process as a means to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs. In addition, public policy permits companies to obtain patents to protect their legitimate intellectual property rights, but patents are not intended to provide a vehicle for companies to create a patent thicket whose very existence is intended only to frustrate other companies' effort to lawfully and legitimately bring products to market. In addition to offending public policy, AbbVie's conduct is also immoral, unethical, oppressive, and unscrupulous.

224. The purposes and effects of this agreement were to: (a) delay and prevent the entry of more affordable biosimilar versions of Humira in the United States; (b) fix, raise, maintain, or stabilize the prices of Humira; and (c) allocate 100% of the U.S. adalimumab market to AbbVie. As a direct and proximate result of AbbVie's unfair and unconscionable conduct, Plaintiff and members of the Damages Class were denied the opportunity to purchase lower-priced biosimilar versions of Humira, were forced to pay higher prices for Humira than they would have had a biosimilar been available, and lost money or property as a result.

225. There was and is a gross disparity between the price that Plaintiff and Damages Class members paid for Humira and the value they received. Much more affordable, biosimilar versions of Humira would have been available sooner and in greater quantity, and prices for

branded Humira would have been lower, but for AbbVie's unfair and unconscionable conduct. Plaintiff and class members purchased, paid and/or provided reimbursement for some or all of the price of Humira for purchases intended primarily for personal, family, and/or household use.

226. AbbVie's conduct was intended to, and did, cause substantial injury to end-payers in the form of denying them the ability to purchase less-expensive biosimilar versions of Humira. Plaintiff and other end-payers could not reasonably have avoided injury from AbbVie's wrongful conduct. AbbVie's conduct occurred in connection with consumer transactions related to the availability and sale of adalimumab products.

227. There are no countervailing benefits to AbbVie's conduct that would outweigh the injury caused to end-payers.

228. AbbVie's conduct violates the following state laws:

A. Alaska

229. The Alaska Unfair Trade Practices and Consumer Protection Act prohibits "unfair . . . acts or practices in the conduct or trade or commerce." ALASKA STAT. ANN. § 45.50.471.

230. By reason of the conduct alleged herein, AbbVie has engaged in unfair methods of competition and unfair acts or practices in the conduct of trade or commerce. ALASKA STAT. ANN. § 45.50.471, *et seq*.

231. Plaintiff and members of the Damages Class purchased Humira within the State of Alaska during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

232. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class suffered an ascertainable loss of money or property and are threatened with further injury.

233. By reason of the foregoing, Plaintiff and the Damages Class are entitled to seek all forms of relief, including up to treble damages, $500 in damages per violation, and reasonable attorneys' fees and costs. ALASKA STAT. ANN. § 45.50.531.

B. Arizona

234. The Arizona Consumer Fraud Act prohibits unfair acts and practices in connection with the sale or advertisement of any merchandise." ARIZ. REV. STAT. § 44-1522(A).

235. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in connection with the sale of Humira and has violated the Arizona Consumer Fraud Act, Section 44-1521, *et seq*.

236. Plaintiff and members of the Damages Class purchased Humira within the State of Arizona during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

237. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

238. By reason of the foregoing, Plaintiff and the Damages Class are entitled to seek all forms of relief, including up to treble damages and reasonable attorneys' fees and costs.

C. California

239. The California Unfair Competition Law prohibits any "unlawful" or "unfair . . . business act or practice." CAL. BUS. & PROF. CODE § 17200.

240. By reason of the conduct alleged herein, AbbVie has engaged in unfair business acts and practices. AbbVie's conduct is also unlawful in that it violates, among other things, the Federal Trade Commission Act, 15 U.S.C. 45, *et seq*. CAL. BUS. & PROF. CODE § 17200, *et seq.*

241. This claim is instituted pursuant to Sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from AbbVie for acts, as alleged herein, that violated the Unfair Competition Law.

242. Plaintiff and members of the Damages Class are entitled to full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by AbbVie as a result of such business acts or practices.

243. The unlawful and unfair business practices of AbbVie, and each of them, as described above, have caused and continue to cause members of the Damages Class to pay supra-competitive and artificially-inflated prices for Humira sold in the State of California. Plaintiff and the members of the Damages Class suffered injury in fact and lost money or property as a result of such unfair competition.

244. As alleged in this complaint, AbbVie has been unjustly enriched as a result of their wrongful conduct and by AbbVie's unfair competition. Plaintiff and the members of the Damages Class are accordingly entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits that may have been obtained by AbbVie as a result of such business practices, pursuant to California Business and Professions Code Sections 17203 and 17204.

D. District of Columbia

245. The District of Columbia Consumer Protection Procedures Act prohibits "any person" from "engag[ing] in an unfair . . . trade practice." D.C. CODE § 28-3904.

246. By reason of the conduct alleged herein, AbbVie has engaged in unfair trade practices in connection with consumer transactions. D.C. CODE § 28-3904, *et seq.*

247. AbbVie is a "merchant" within the meaning of D.C. Code § 28- 3901(a)(3).

248. AbbVie's unlawful conduct substantially affected the District of Columbia's trade and commerce.

249. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and members of the Damages Class have been injured in their business or property and are threatened with further injury.

250. By reason of the foregoing, Plaintiff and members of the Damages Class are entitled to seek all forms of relief, including treble damages or $1500 per violation (whichever is greater) plus punitive damages, reasonable attorney's fees and costs under D.C. Code § 28-3901, *et seq.*

E. Florida

251. The Florida Deceptive & Unfair Trade Practices Act prohibits "unconscionable acts or practices" and "unfair . . . act or practices in the conduct of any trade or commerce." FLA. STAT. § 501.204.

252. By reason of the conduct alleged herein, AbbVie has engaged in unconscionable and unfair acts and practices in the conduct of trade and commerce. FLA. STAT. § 501.204, *et seq.*

253. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." FLA. STAT. § 501.202(2).

254. Members of the Damages Class purchased Humira within the State of Florida during the class period. But for AbbVie's conduct set forth herein, the price of Humira or biosimilar versions of Humira would have been lower, in an amount to be determined at trial.

255. AbbVie's unlawful conduct substantially affected Florida's trade and commerce.

256. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property by virtue of overcharges for Humira and are threatened with further injury.

257. By reason of the foregoing, Plaintiff and the members of the Damages Class are entitled to seek all forms of relief, including injunctive relief pursuant to Florida Statutes § 501.208 and declaratory judgment, actual damages, reasonable attorneys' fees and costs pursuant to Florida Statutes § 501.211.

F. Georgia

258. The Georgia Fair Business Practices Act prohibits "unfair . . . acts or practices." GA. CODE ANN. § 10-1-393.

259. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce. GA. CODE ANN. § 10-1-393, *et seq*.

260. AbbVie's unlawful conduct substantially affected Georgia's trade and commerce.

261. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury

262. By reason of the foregoing, Plaintiff and members of the Damages Class are entitled to seek all forms of relief available under GA. CODE ANN. § 10-1-399, *et seq*.

G. Illinois

263. The Illinois Consumer Fraud and Deceptive Business Practices Act prohibits "unfair . . . acts or practices." 815 ILCS § 505/2.

264. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices. 815 ILCS § 505/2, *et seq.* AbbVie's conduct was directed at the market generally and implicates the welfare of consumers

265. AbbVie's unlawful conduct substantially affected Illinois's trade and commerce.

266. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and members of the Damages Class were actually deceived and have been injured in their business or property and are threatened with further injury.

267. By reason of the foregoing, Plaintiff and members of the Damages Class are entitled to seek all forms of relief, including actual damages or any other relief the Court deems proper under 815 Illinois Compiled Statutes 505/10a, *et seq*.

H. Nebraska

268. The Nebraska Consumer Protection Act prohibits "unfair . . . acts or practices in the conduct of any trade or commerce." NEB. REV. ST. § 59-1602.

269. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in the conduct of trade or commerce.

270. AbbVie's unlawful conduct substantially affected Nebraska's trade and commerce.

271. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

272. By reason of the foregoing, Plaintiff and members of the Damages Class are entitled to seek all forms of relief available under Nebraska Revised Statutes § 59- 1614.

I. Nevada

273. The Nevada Deceptive Trade Practices Act prohibits companies from engaging in conduct that violates "a state or federal statute or regulation relating to the sale or lease of goods or service." N.R.S. § 598.0923.

274. By reason of the conduct alleged herein, AbbVie's conduct violates state and federal law, in particular the Federal Trade Commission Act, 15 U.S.C. 45, *et seq*.

275. AbbVie's unlawful conduct substantially affected Nevada's trade and commerce.

276. AbbVie's conduct was willful.

277. As a direct and proximate cause of AbbVie's unlawful conduct, the members of the Damages Class have been injured in their business or property and are threatened with further injury.

278. By reason of the foregoing and pursuant to N.R.S. § 41.600, the Damages Class is entitled to seek all forms of relief, including damages, reasonable attorneys' fees and costs, and a civil penalty of up to $5,000 per violation under Nevada Revised Statutes § 598.0993.

J. New Hampshire

279. The New Hampshire Consumer Protection Act prohibits "any unfair . . . act or practice in the conduct of any trade or commerce." N.H. REV. STAT. § 358-A:2

280. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in the conduct of trade or commerce and has violated N.H. REV. STAT. § 358-A:2, *et seq*.

281. AbbVie's conduct was willful and knowing.

282. AbbVie's unlawful conduct substantially affected New Hampshire's trade and commerce.

283. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

284. By reason of the foregoing, Plaintiff and the members of the Damages Class are entitled to seek all forms of relief available under New Hampshire Revised Statutes §§ 358-A:10 and 358-A:10-a.

K. New Mexico

285. The New Mexico Unfair Practices Act prohibits "unfair . . . trade practices and unconscionable trade practices in the conduct of any trade or commerce." N.M.S.A. § 57-12-3.

286. By reason of the conduct alleged herein, AbbVie has engaged in unfair and unconscionable trade practices in the conduct of trade or commerce and has violated N.M.S.A. § 57-12-3, *et seq.*

287. AbbVie's conduct constituted "unconscionable trade practices" in that such conduct resulted in a gross disparity between the value received by the New Mexico Damages Class members and the price paid by them for Humira as set forth in New Mexico Statutes § 57-12-2E.

288. AbbVie's conduct was willful.

289. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

290. By reason of the foregoing, Plaintiff and members of the Damages Class are entitled to seek all forms of relief, including actual damages or up to $300 per violation, whichever is greater, plus reasonable attorney's fees under New Mexico Statutes § 57-12-10.

L. North Carolina

291. The North Carolina Unfair Trade and Business Practices Act prohibits "unfair . . . acts or practices in or affecting commerce." N.C. GEN. STAT. § 75-1.1

292. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices affecting commerce and has violated N.C. GEN. STAT. § 75-1.1, *et seq*. AbbVie's conduct is offensive to public policy and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers

293. AbbVie's conduct constitutes consumer-oriented acts or practices within the meaning of North Carolina law, which resulted in consumer injury and broad adverse impact on the public at large and harmed the public interest of North Carolina consumers.

294. Plaintiff and members of the Damages Class purchased Humira within the State of North Carolina during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

295. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

296. By reason of the foregoing, Plaintiff and the members of the Damages Class are entitled to seek all forms of relief, including treble damages under North Carolina General Statutes § 75-16.

M. North Dakota

297. The North Dakota Unfair Trade Practices Law prohibits "the act, use, or employment . . . of any act or practice . . . which is unconscionable" NDCC § 51-15-02.

298. By reason of the conduct alleged herein, AbbVie has engaged in unconscionable acts and practices and has violated NDCC § 51-15-02, *et seq*.

299. AbbVie's unlawful conduct substantially affected North Dakota's trade and commerce.

300. AbbVie's conduct was willful.

301. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

302. By reason of the foregoing, Plaintiff and the members of the Damages Class are entitled to seek all forms of relief, including damages and injunctive relief under NDCC § 51-10-06.

N. South Carolina

303. The South Carolina Unfair Trade Practices Act prohibits "unfair . . . acts or practices in the conduct of any trade or commerce." S.C. CODE ANN. § 39-5-20.

304. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in the conduct of trade or commerce and has violated South Carolina Code § 39-5-10, *et seq*. AbbVie's conduct is offensive to public policy and is immoral, unethical, and oppressive.

305. AbbVie's unlawful conduct substantially affected South Carolina's trade and commerce.

306. Plaintiff and members of the Damages Class purchased Humira within the State of South Carolina during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

O. Utah

307. The Utah Consumer Sales Practices Act prohibits any "unconscionable act or practice." UTAH CODE ANN. § 13-11-5.

308. By reason of the conduct alleged herein, AbbVie has engaged unconscionable acts and practices in connection with consumer transactions. UTAH CODE ANN. § 13-11-5, *et seq.*

309. Plaintiff and members of the Damages Class purchased Humira within the State of Utah during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

310. AbbVie knew or had reason to know that their conduct was unconscionable.

311. AbbVie's unlawful conduct substantially affected Utah's trade and commerce.

312. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

313. By reason of the foregoing, the Plaintiff and the members of the Damages Class are entitled to seek all forms of relief, including declaratory judgment, injunctive relief, damages, and ancillary relief, pursuant to Utah Code Ann. §§ 13-11-19(5) and 13-11-20.

P. West Virginia

314. The West Virginia Consumer Credit and Protection Act prohibits "unfair . . . acts or practices in the conduct of any trade or commerce." W. VA. CODE § 46A-6-104.

315. By reason of the conduct alleged herein, AbbVie has engaged in unfair acts and practices in the conduct of trade or commerce and has violated Section 46A-6-101, *et seq.* of the West Virginia Code.

316. Plaintiff and members of the Damages Class purchased Humira within the State of West Virginia during the class period. But for AbbVie's conduct set forth herein, the price paid would have been lower, in an amount to be determined at trial.

317. As a direct and proximate cause of AbbVie's unlawful conduct, Plaintiff and the members of the Damages Class have been injured in their business or property and are threatened with further injury.

318. As a result of AbbVie's violation of Section 47-18-3 of the West Virginia Antitrust Act, Plaintiff and members of the Damages Class seek all recoverable damages and their cost of suit, including reasonable attorneys' fees, pursuant to Sections 46A-5-101(a) and 46A-5-104 of the West Virginia Code.

XII. DEMAND FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully demands that the Court:

i. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. Rule 23(a), (b)(2), and (b)(3), direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Class, and declare Plaintiff as a named representative of the Class;

ii. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

iii. Enter judgment against AbbVie and in favor of Plaintiff and the Class;

iv. Award damages (*i.e.*, three times overcharges) to the Damages Class in an amount to be determined at trial, plus interest in accordance with law;

v. Award Plaintiff and the Damages Class their costs of suit, including reasonable attorneys' fees as provided by law;

vi. Enter injunctive relief to stop AbbVie's unlawful conduct; and

vii. Award such further and additional relief as is necessary to correct for the anticompetitive market effects AbbVie's unlawful conduct caused and as the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: March 29, 2019

Respectfully submitted,

/s/ *Lisa B. Weinstein*

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